Water Management Program

IDAC Fall 2022

Shane Sullivan, Vice President of Sales

NEPHROS

“In wine there is wisdom, in beer there is freedom, in water there is .....”

- Benjamin Franklin

Shane Sullivan, Vice President Of Sales

- 20+ years in healthcare, life-science and bio-pharma
- Water filtration expert
  - Infection Prevention
  - Dialysis
  - Emergency Response
- Board, APIC Greater Los Angeles Chapter
- Board, California APIC Coordinating Council

- University of Southern California (BS)

Water Management Requirements For Healthcare Facilities

Historical Perspective

1976 Legionnaires Disease (LD) Outbreak – Bellevue Stratford Hotel, Philadelphia
1981 Link between LD and hospital potable water first recognized (SP Fischer-Hoch et al.)
2000 ASHRAE Guideline 12-2000
2004 L. pneumophila genome is deciphered (Shuman Lab, Columbia University)
2015 ASHRAE 188-2015 (Revised 2018) *39 years
2015 NYS Regulation – Protection Against Legionella
2017 CDC Toolkit (ASHRAE Standard 188)
2017 CMS S&C Memo EC.02.05.01 (Revised 2018) *41 years
2020 ASHRAE Guideline 12-2020
2020 The Joint Commission – Draft NEW Requirements/Public Comment
2021 CDC Toolkit (ASHRAE Guideline 12-2020)
2021 ASHRAE 514P – Advisory Public Review (2021)
2021 The Joint Commission – Pre-publication (March 2021)NEW Requirements
2022 CMS / TJC EC.02.05.02 (Effective January 1, 2022) *46 years!

Water Management Regulations

- 2017/18 CMS/TJC EC.02.05.01:
  - 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**

- **2022 CMS/TJC EC.02.05.02:**
  - **Revisit — water management team**
  - **Patient Population / Risk**
  - **Control Measures**
  - **Corrective Action (Emergency Response)**
  - **Ice machines treated as critical control points**
  - **Program validation / DOCUMENTATION!**

Pathogens of concern:

Legionella

Pseudomonas

Nontuberculous Mycobacteria (NTM)

E-Coli

Acinetobacter

Burkholderia

Klebsiella

Acanthamoeba

Hartmanella

Stenotrophomonas

Elizabethkingia

Are You Prepared?

CMS/TJC EC.02.05.02
January 1, 2022

Legionella bacteria found in hospital ice machines at UPMC Presbyterian

LUIS FÁBREGAS AND ADAM SMELTZ | Friday, May 2, 2014, 12:03 a.m.

TRIB TOTAL MEDIA

The main entrance of UPMC Presbyterian in Oakland.

Legionella bacteria in ice machines at UPMC Presbyterian contributed to one patient's death and sickened two others, hospital officials disclosed on Thursday, calling it an unusual episode uncovered because a patient aspirated ice chips.

TOP STORY

Dozens of Roper Hospital patients developed waterborne bacterial infection after surgery

By Lauren Sausser lsausser@postandcourier.com Apr 13, 2018 (...)

Roper Hospital on Calhoun Street identified that its water supply was tainted with bacteria that infected more than two dozen women following breast reconstruction surgery. File/Staff

Buy Now

News > Medscape Medical News

Maryland NICU Still Taking Action After *Pseudomonas* Exposure

Alicia Ault
August 18, 2016

1 Read Comment

A hospital in the Washington, DC, suburbs is treating the plumbing and disinfecting the neonatal intensive care unit (NICU) after three neonates tested positive for the potentially deadly *Pseudomonas aeruginosa* bacteria.

In consequence, these all can lead to adverse **pregnancy** outcomes such as preterm birth and even neonatal sepsis. ... **Klebsiella pneumoniae** may be cause of sepsis in the newborn, mainly in patients with some predisposing factors, including prematurity or those carrying an intravenous catheter. Jan 29, 2015

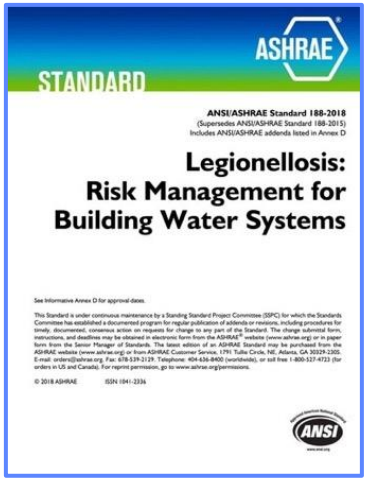
academic.oup.com › femsle › article

First report of a Klebsiella pneumoniae ST466 strain causing ...

How comprehensive is your water management plan today?

Resources:

- ASHRAE 188 guideline/standard of care (*Legionella* only)
- 2017 CMS regulation impacting close to 20,000 facilities nationally, NOW!
- Joint commission's revised water management standard (ec.02.05.02, eps 1 through 4)
  - Water management team
  - Corrective action plan
  - Ice machines
  - Program validation
- CDC toolkits / CDC guidance (WICRA)



ASHRAE STANDARD

ANSI/ASHRAE Standard 188-2018
(Supersedes ANSI/ASHRAE Standard 188-2015)
Includes ANSI/ASHRAE addenda listed in Annex D

Legionellosis: Risk Management for Building Water Systems

See Informative Annex D for approval dates.

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 procedures for timely, documented, consensus action on requests for change to any part of the Standard. The change submittal form, instructions, and deadlines may be obtained in electronic form from the ASHRAE® website (www.ashrae.org) or in paper form from the Senior Manager of Standards. The latest edition of an ASHRAE Standard may be purchased from the ASHRAE website (www.ashrae.org) or from ASHRAE Customer Service, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: orders@ashrae.org. Fax: 678-539-2129. Telephone: 404-636-8400 (worldwide), or toll free 1-800-527-4723 (for orders in US and Canada). For reprint permission, go to www.ashrae.org/permissions.

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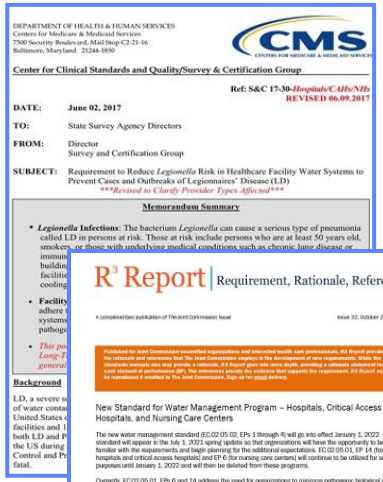


DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-30-*Hospitals/CAHs/NHs*
REVISED 06.09.2017

DATE: June 02, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

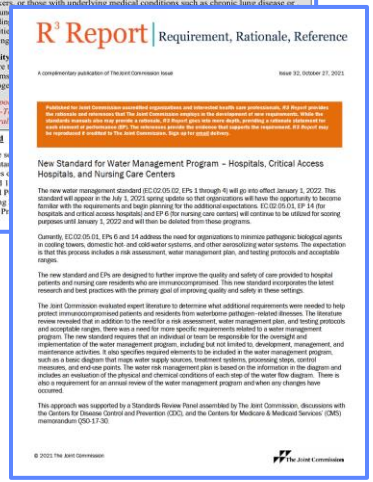
SUBJECT: Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)
****Revised to Clarify Provider Types Affected****

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 immun
- **Facility** adhere t systems pathoge
- *This pa Long-T general*

Background

LD, a severe s of water conta United States facilities and both LD and P the US during Control and Pr fatal.



R³ Report | Requirement, Rationale, Reference

A complimentary publication of The Joint Commission Issue

Issue 32, October 27, 2021

Published for Joint Commission accredited organizations and interested health care professionals, R3 Report provides the rationale and references that The Joint Commission employs in the development of new requirements. While the standards manuals also may provide a rationale, R3 Report goes into more depth, providing a rationale statement for each element of performance (EP). The references provide the evidence that supports the requirement. R3 Report may be reproduced if credited to The Joint Commission. Sign up for email delivery.

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

The new water management standard (EC.02.05.02, 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.

The Joint Commission evaluated expert literature to determine what additional requirements were needed to help protect immunocompromised patients and residents from waterborne pathogen–related illnesses. 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.

This approach was supported by a Standards Review Panel assembled by The Joint Commission, discussions with the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services' (CMS) memorandum QSO-17-30.

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The Joint Commission

Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems to reduce the risk of growth and spread of Legionella and other opportunistic pathogens in water

REVIEW: A Few Basics About Water Management In Buildings

The drinking water supply is <u>not</u> sterile

Building water systems can act as incubators where pathogens grow

Building water systems can transmit pathogen-contaminated water

Pathogens Of Clinical Concern

Drinking water has a rich, diverse microbial community, including many biofilm-associated pathogens of clinical concern, especially in healthcare settings

Bacteria	Protozoa	Viruses
• *Legionella*	• *Giardia*	• Norovirus
• *Pseudomonas*	• *Cryptosporidium*	• Rotavirus
• *Nontuberculosis Mycobacteria*	• *Toxoplasma Gondii*	• Hepatitis-A
• *E. Coli*		

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

Sediment, **T**emperature, Water **A**ge and Disinfectant **R**esidual (**STAR**©) are key conditions that support microbial growth in building water systems

The Objective Of Water Management: Protect People

ESTABLISH
Microbial Control

MAINTAIN
Microbial Control

Measures are sometimes taken to protect building occupants while **establishing and confirming that microbial control** has been established, especially during **outbreak investigations**, including but not limited to:

- Restricting water use
- Installing point-of-use or in-line filters on aerosolizing devices (e.g., showers)
- Distributing bottled water (or filtered-water from “filling stations”)

ASHRAE 188 Methodology

- Team
- System description
- Analysis of building water systems
- Control measures
- Monitoring/Corrective actions
- Confirmation (verification & validation)
- Documentation

The analysis of building water systems, control measures and validation centers on physical & chemical (STAR) conditions that can be measured and managed in real time

Special Considerations For Water Management In Hospitals

Challenges

- Complex plumbing systems — STAR conditions
- Vulnerable patient populations
- Medical devices & procedures that use water
- Multiple waterborne pathogens of concern

Resources

- Highly-trained facilities engineers & operations personnel
- Established infection prevention & control (IP&C) programs
- Clinical services

Key Provisions Of TJC Requirements

- **Multiple pathogens**
  - Reaffirms multi-pathogen scope of CMS S&C memo
  - Consistent with CDC toolkits and guidance
  - Aligns with ASHRAE 514P
- **Parametric validation is required (STAR)**
  - Measurement of physical-chemical conditions throughout the system
  - Consistent with ASHRAE 188-2018
  - Consistent with ASHRAE guideline 12-2020
  - Consistent with CDC toolkits & guidance
- Microbial validation <u>is not required</u>
  - Consistent with ASHRAE 188-2018
  - Consistent with ASHRAE guideline 12-2020
  - Consistent with CDC toolkits & guidance

The Joint Commission does not recommend against testing

Consistent with ASHRAE 188 and CDC Guidance, TJC defers to the judgement of the team on when, how and where to test and for which pathogens

Microbial Testing

Limitations

- Microbial testing is not a control measure
- Legionella culture results do not predict disease or correlate with risk
- Many pathogens of concern cannot be readily detected by culture *These are referred to as viable but not culturable “VBMC”

Proper Use

- Multi-pathogen microbial screening can help focus and establish a baseline for water management plans
- Routine microbial screening/testing can help confirm that a water management plan is effectively controlling hazardous conditions that support the growth of target pathogens
- Microbial testing is an essential tool for investigating suspected cases of disease

Practical Implications – EP1: Team

Consistent with ASHRAE 188 and CDC Guidance, the membership of the water management team in a hospital should draw on multiple disciplines, including:

- Senior Leadership
- Facilities Engineering & Operations
- Infection Prevention & Control
- Nursing/Clinical Services
- Compliance
- Other Departments (Dialysis, Bio-medical, Central Sterile Processing…)

Practical Implications – EP2: System Description

The system description should include details and location/map (diagram) of:

- All water system equipment/components
- All water use end points
- All areas designated for specialized purposes
- All areas designated for specialized patient care
- All medical devices & procedures that use water (or are rinsed with water)
- All drains in areas near patients, medications and sterile supplies
- All non-potable uses fed by the potable water system

Practical Implications – EP2: Building Water Systems

The analysis of the building water systems should include:

- A step-by-step evaluation of all water use end points, all plumbing equipment and all pipes for STAR conditions that, in the absence of control, could support growth of pathogens
- Identify any areas where **potentially hazardous conditions** may occur (these conditions can most likely occur in areas with **slow or stagnant water**)
- A description and **location of every point in the system where water can be aerosolized or splashed (Sinks, Showers, etc.)**
- A description and **location of every point in the system where medications are prepared**, or **sterile supplies or medical devices are processed or stored**
- **A ranking of patients receiving specialized care** (e.g., BMT, burns, chemotherapy) for relative vulnerability to the microbial pathogens of concern

Practical Implications – EP2: Control Measures

Control measures should include means for managing growth supportive (STAR) conditions:

- **S**ediment – flushing, blowdown, preventive & predictive maintenance
- **T**emperature – water storage, distribution and delivery temperatures
- Water **A**ge (and dead-legs) – flushing, blowdown

In general, the control measures used to manage sediment, temperature and water age are effective for inhibiting growth of legionella and the other pathogens that are within the scope of CMS/TJC requirements for hospitals. Supplemental disinfection requires special consideration

Practical Implications – EP2: Control Measures

Control measures may also include continuous supplemental disinfection (CSD)

CAUTION

ASHRAE Guideline 12-2020 Section 5.2.3.1 lists factors that should be considered when reviewing options for supplemental disinfection including potential Unintended consequences, such as:

- Promoting growth of some pathogens
- Formation of toxic disinfection byproducts
- Significant adverse impact on materials

Practical Implications – EP2: Control Measures (note 1)

Control measures also should include means for preventing contamination of:

- Medical devices that **use water**
- Devices and equipment that are **washed/rinsed with water**
- Near Medication and sterile supplies

These and similar devices/equipment should use or be rinsed with water that meets AAMI TIR34:2014 Water for The Reprocessing of Medical Devices

Practical Implications – EP2: Control Measures (cont.)

Protective measures, when used routinely, are sometime referred to as control measures. These include:

- Point-of-use or in-line filters on sink and showers near highest-risk patients
- In-line filters on ice machines
- Point-of-use filters and splash guards near areas where medication is prepared, or sterile supplies are stored

Point-of-use & in-line filters should be FDA 510k-Cleared Class II to aid in infection control

Filters used to block bacteria should also meet ASTM F838 Standard Test Method for determining bacterial retention of membrane filters utilized for liquid filtration. To block transmission of viruses and endotoxins, filters should meet AAMI TIR34:2014 Water for The Reprocessing of Medical Devices.

Practical Implications – EP2: Control Measures (note 2)

Tap water should never be used in medical devices that use water and **should not be used to wash or rinse any devices, equipment or surfaces with which patients may have direct or indirect contact**. Devices or equipment that use water should be clearly labeled, "DO NOT USE TAP WATER". These include:

- CPAP machines
- Endoscopes
- Heater-cooler units
- Hydrotherapy equipment
- Ice machines
- Mechanical ventilators

Practical Implications – EP2: Monitoring

Parametric validation (required by TJC) involves measuring physical-chemical characteristics of the water at representative points throughout all areas of the hospital served by the building water systems. These parameters include:

- Temperature
- Ph
- Residual disinfectant
- Microbial Validation (optional)

Practical Implications – Microbial Validation

Microbial validation (optional) involves collecting water samples from representative points throughout all areas of the hospital served by the building water systems and analyzing the samples for microbial pathogens.

In the past, for water management programs that addressed only legionella, culture for legionella spp. Notwithstanding method limitations– provided a reasonable means for microbial validation.

Practical Implications – EP3: Documentation

Documenting RESULTS of ALL MONITORING activities

Documenting **corrective actions** taken when **control limits** are not maintained

Corrective actions and procedures to follow if a test result outside of acceptable limits is obtained, including when a probable or confirmed waterborne pathogen(s) indicates action is necessary

Practical Implications – EP4: Review & Changes

Water Management Plan must be reviewed and updated **ANNUALLY** and when the following occurs:

Changes have been made to the water system in the past 12-months that would add additional risk.

New equipment or at-risk water system(s) has been added that could generate aerosols or be a potential source for Legionella. This includes the commissioning of a new wing or building.

Practical Implications – CDC Guidance

Growth Supportive Conditions	x	Location of Transmission Sources	x	Risk-ranked Patient Populations	=	RISK

Comprehensive CDC Water Infection Control Risk Assessments (WICRA) are facilitated by the new TJC Requirements for Water Management in Hospitals, as understood in the context of the referenced ASHRAE & CDC documents

Summary

Consistent with TJC principles, the new requirements:

- Complement ongoing hospital efforts and existing WM programs
- Consider multiple pathogens, consistent with best IP&C practices
- Focus on control of water parameters that can be measured and managed by healthcare facility engineers
- Are consistent with the recommendations and guidance of industry consensus standards (ASHRAE) and leading public health agencies (CDC)

Acknowledgements

- **Aaron Rosenblatt** — Rosenblatt & Associates
- **Matthew Arduino** — CDC
- **David Dziewulski** — NY DOH
- **Jonathan Flannery** — ASHE
- **Sylvia Garcia-Houchins** — TJC

Please note: this acknowledgement should not be construed as an endorsement of any of the content by the acknowledged individuals or their organizations

Ice Machines - a source of transmission?

Legionella bacteria found in hospital ice machines at UPMC Presbyterian

LUIS FÁBREGAS AND ADAM SMELTZ | Friday, May 2, 2014, 12:03 a.m.

TRIB TOTAL MEDIA

The main entrance of UPMC Presbyterian in Oakland.

Legionella bacteria in ice machines at UPMC Presbyterian contributed to one patient's death and sickened two others, hospital officials disclosed on Thursday, calling it an unusual episode uncovered because a patient aspirated ice chips.

Ice maker, sinks linked to UW Medical Center Legionnaires' outbreak; 2 dead

Staff - Thursday, September 15th, 2016

Save Post Tweet Share Listen Text Size Print Email

After extensive testing throughout University of Washington Medical Center, the source of a Legionnaires' disease outbreak was located in the Seattle-based hospital Tuesday evening, according to the *Seattle Times*, but not before a second patient with the infection died.

The hospital started searching for the source of the infections after two patients tested positive for *Legionella*, the bacteria that causes Legionnaires' disease. One of those patients died Sept. 8.

Now, a third patient has been linked to the Legionnaires' disease outbreak. This patient died Aug. 27, but the connection to *Legionella* was not made until the autopsy, according to a Public Health-Seattle & King County blog post. The bacteria may have contributed to this patient's death.

The subsequent investigation revealed Legionella bacteria was dwelling in an ice machine and two sinks in UW Medical Center's cardiac unit in its Cascade tower. Patients, visitors and staff have been instructed to not use drinking fountains on the unit, and the hospital shipped in bottled water to use in the interim. The water system could be off-limits for at least two weeks, according to the *Seattle Times*.

Original Article | Published: 18 November 2017

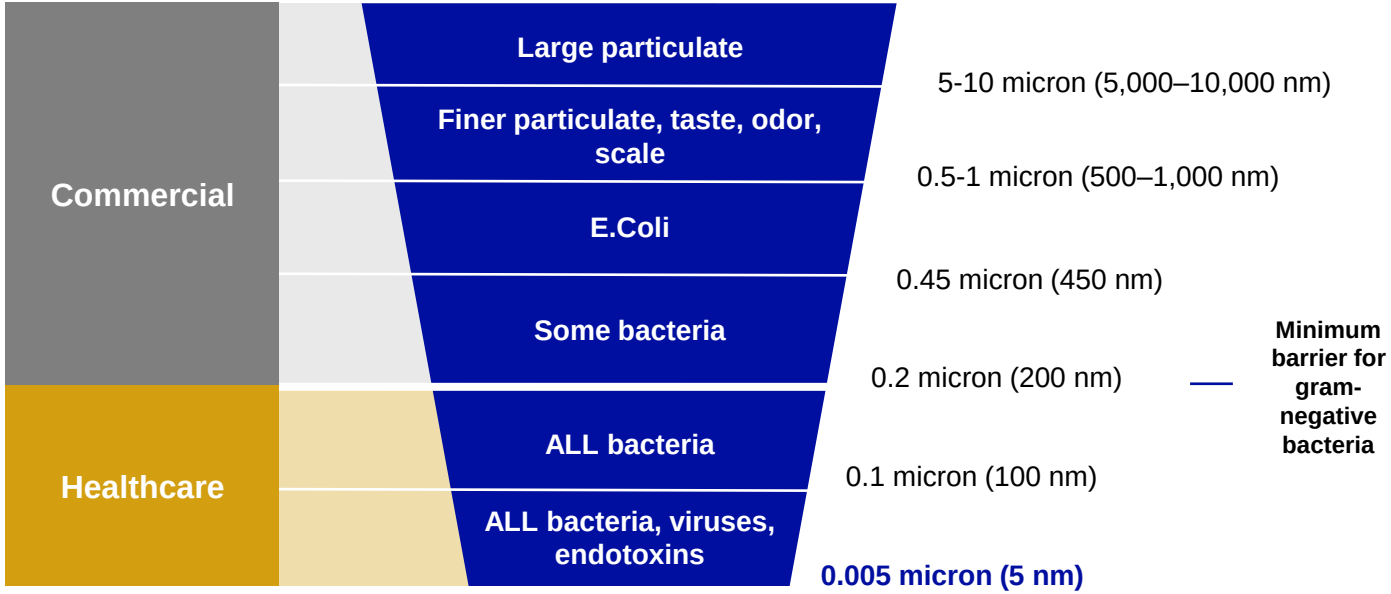
Presence of pathogenic bacteria in ice cubes and evaluation of their survival in different systems

Luca Settanni, Raimondo Gaglio, Carlo Stucchi, Simone De Martino, Nicola Francesca & Giancarlo Moschetti

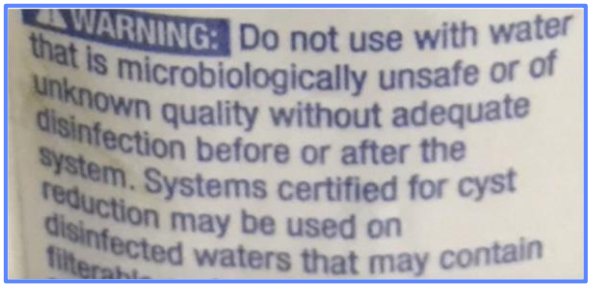
Annals of Microbiology **67**, 827–835 (2017) | Cite this article

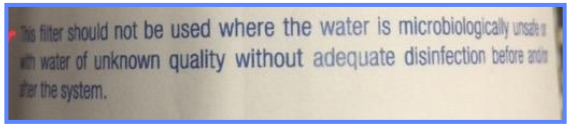
2157 Accesses | **7** Citations | **132** Altmetric | Metrics

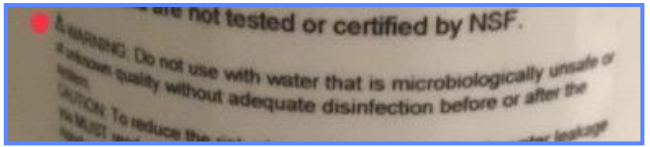
Ice Machine Filtration

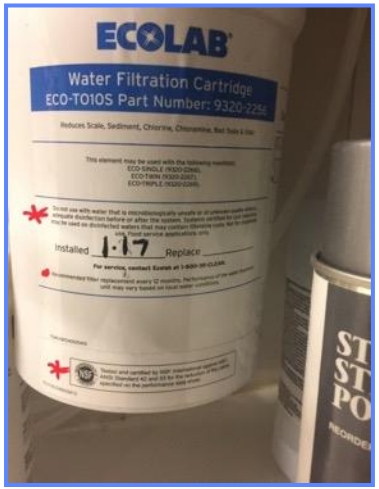


Must Read The Fine Print





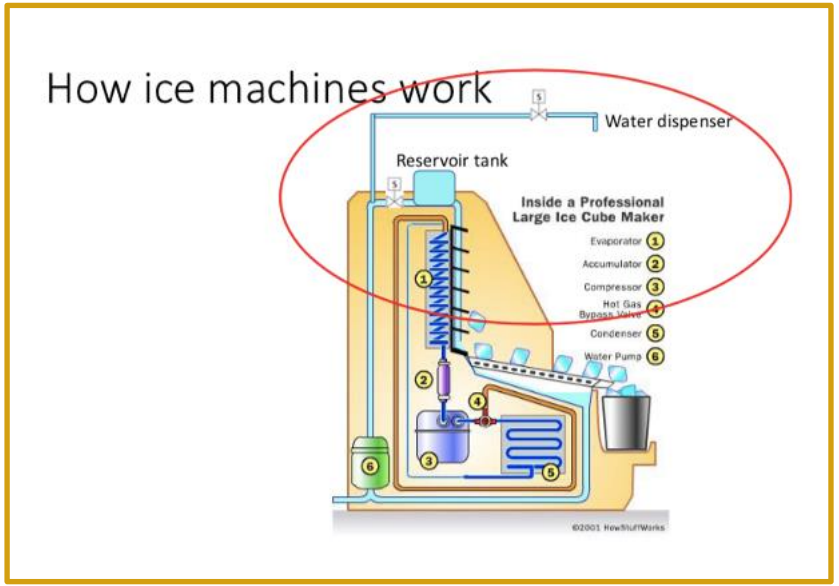




"I'm incapable of providing a barrier to bacteria, viruses and endotoxins"

Ice Machines

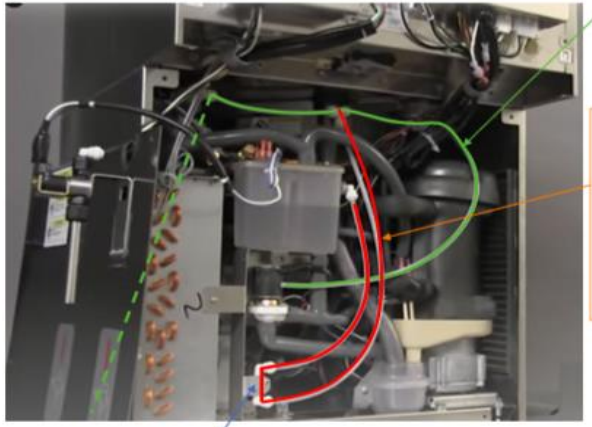
3-12'



Blind Spot: Supply Lines

Ice Machine Cleaning: Room For Improvement

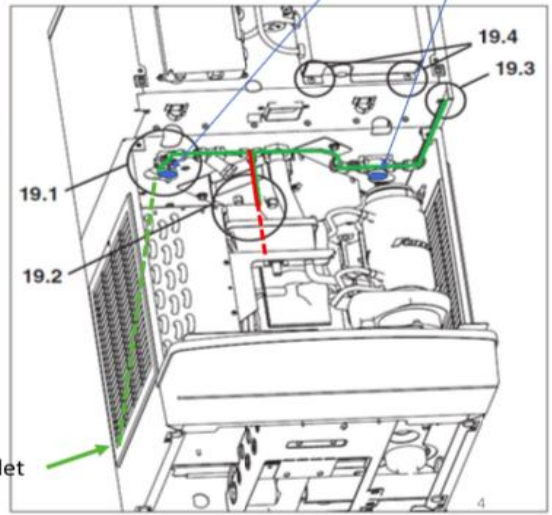
- **Follett 25ci425a**



(Green) Line to water dispenser sanitized with current AEM

(Red) Line to ice maker reservoir tank not sanitized with current AEM

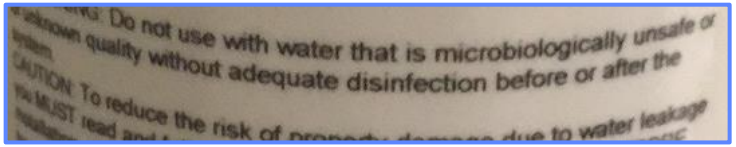
Solenoid valve?



These conditions also apply to drinking fountains and hydration stations!

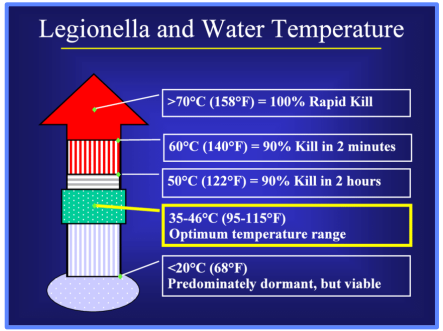
What Are The Gaps In Your Cleaning Process?

- Three-step process (3-4 hours)
- Focused on “bin to dispenser”
- Are your supply lines addressed?
- Is your de-scaling fluid diluted with warm or hot tap water?
- Is your sanitizer diluted with tap water?
- What’s the problem with rinsing with “fresh tap water”?



Water Temperature

- ***Legionella*, and all other opportunistic waterborne bacteria, are impacted by water temperatures**
- It is important to keep water temperatures out of the **growth range of 68-122F**
  - Keep cold water <68F
  - Keep hot water >122F



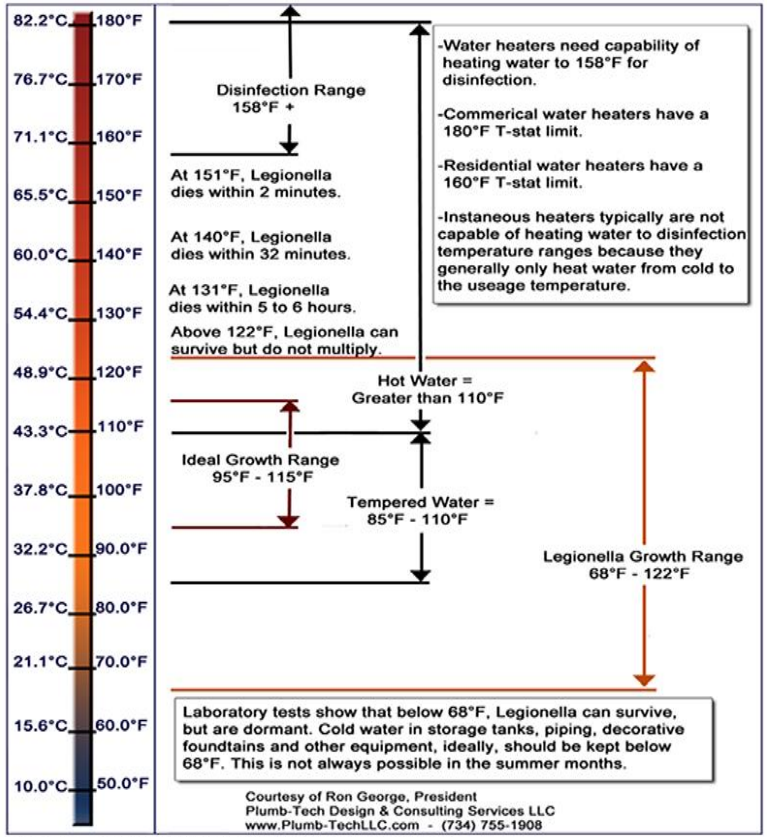
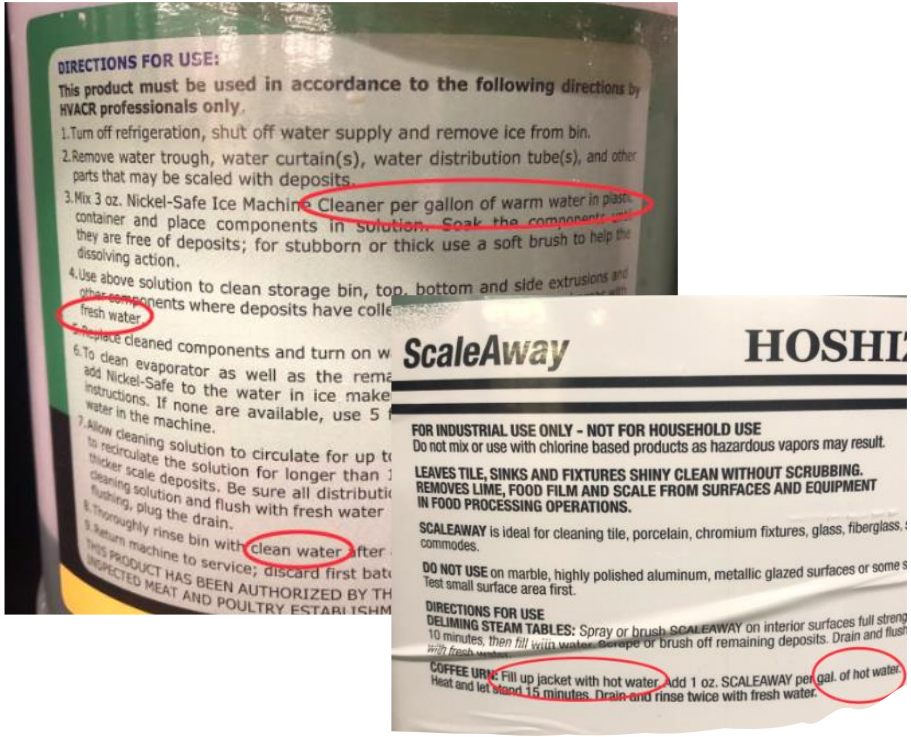


Figure 1 – Legionella Bacteria Growth Temperatures
Source: www.legionellaprevention.org

Recommendations

- Dilute de-scaling fluid with **filtered water**
- Dilute sanitizing fluid with **filtered water**
- Rinse equipment with **filtered water**



Ice machine / equipment cleaning stations should ALWAYS have filtered water

Panel Discussion On Ice Machines

- **Lisa Kilgore** — Scripps Health
- **Kai Bryant** — Scripps Health
- **Shane Sullivan** — Nephros

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Thank you

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