North Texas Chapter of NANT
20th Annual North Texas DTX
“Dialysis Tech ConnXion”

New Standard to Control Opportunistic Organisms
ASHREA 188 – New Standard to Control Opportunistic Organisms
(Compliance for Hemodialysis Water Treatment Facilities)

by Burke A. West, PE, MWS, Pres. Nelson Environmental Technologies, Inc.

Sunday, November 17, 2019 10:30 – 12:00
Sheraton Arlington Hotel 1500 Convention Center Drive Arlington, Texas 76011
This presentation will include:

1. Background of Legionella and other Opportunistic Bacteria
2. ASHRAE 188
3. CDC Legionella tool kit & Water Management Plan
4. CMS regulation
5. Implementation of Water Management Plan
6. Future
Opportunistic

op·por·tun·is·tic
/ˌäpərt(y)ōnˈnistik/

adjective

exploiting chances offered by immediate circumstances without reference to a general plan or moral principle.

From Oxford
Opportunistic

op·por·to·nis·tic
ˌōpərˈtənəstik/
Adjective

So it would appear from this definition that bacteria are amoral. No moral discipline!
Opportunistic

Op·por·tu·nis·tic
/ˌäpərt(y)əˈnɪstɪk/
Adjective

MEDICINE
of a microorganism (or an infection caused by it) rarely affecting patients except in unusual circumstances, typically when the immune system is depressed.

From Oxford
Opportunistic Bacteria

Opportunistic bacteria are defined, for the purposes of this presentation, as those that:

1. Thrive in water at or near human body temperature 37°C (98.6°F);
2. Propagate in waters associated with medical or industrial equipment systems;
3. Are transported by water vapor typically generated by fans, misters, or other mechanical devices.
Legionella

Legionella bacteria are the best known of this type of bacteria; and as such, we will use the term **Legionella** to represent all of the bacteria that fall into the opportunistic category.
Legionella Disease (LD)

• The term **Legionella Disease (LD)** will be used for the disease caused by all of the bacteria that fall into this category.
Back Ground (ASHRAE 188 & CMS)

• ASHRAE: American Society of Heating, Refrigeration, and Air Conditioning Engineers
• CMS: Centers for Medicare & Medicaid Services
• In 1976, Legionella disease was discovered after many participants at an American Legion convention came down with the pneumonia-type disease.
Back Ground (ASHRAE 188 & CMS)

• **In 2005,** ASHRAE began working on the guideline SPC-188 which eventually became the Standard 188-2015.

• **On June 26, 2015** ASHRAE published Standard ASHRAE 188: Risk Management for Building Water Systems
Back Ground (ASHRAE 188 & CMS)

• In 2017 the CDC published, “Developing a Water Management Program to Reduce Legionella Growth & Spread in Buildings”.
Back Ground (ASHRAE 188 & CMS)

• On June 2, 2017 DHHS, CMS advised State Survey Agency Directors:

• “CMS expects Medicare certified healthcare facilities to have water management policies and procedures to reduce the risk of growth and spread of Legionella and other opportunistic pathogens in building water systems.”
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 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.

Background

LD, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium Legionella. In a recent review of LD outbreaks in the United States occurring in 2000–2014, 19% of outbreaks were associated with long-term care facilities and 15% with hospitals. The rate of reported cases of legionellosis, which comprises both LD and Pontiac fever (a milder, self-limited, influenza-like illness) has increased 286% in the US during 2000–2014, with approximately 5,000 cases reported to the Centers for Disease Control and Prevention (CDC) in 2014. Approximately 9% of reported legionellosis cases are fatal.
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland  21244-1850

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***
Page 2 – State Survey Agency Directors

The Centers for Medicare & Medicaid Service (CMS) is aware of multiple recent LD outbreaks in hospitals and long-term care facilities as reported by the CDC, state and local health departments, or investigated by State Survey Agencies (SA).

Outbreaks generally are linked to environmental reservoirs in large or complex water systems, including those found in healthcare facilities such as hospitals and long-term care facilities. Transmission from these water systems to humans requires aerosol generation, as can occur from showerheads, cooling towers, hot tubs, and decorative fountains. *Legionella* is less commonly spread by aspiration of drinking water or ice. Only one case of possible person-to-person transmission has been reported.

In manmade water systems, *Legionella* can grow and spread to susceptible hosts, such as persons who are at least 50 years old, smokers, and those with underlying medical conditions such as chronic lung disease or immunosuppression. *Legionella* can grow in parts of building water systems that are continually wet, and certain devices can spread contaminated water droplets via aerosolization. Examples of these system components and devices include:

- Hot and cold water storage tanks
- Water heaters
- Water-hammer arrestors
- Pipes, valves, and fittings
- Expansion tanks
- Water filters
- Electronic and manual faucets
- Aerators
- Faucet flow restrictors
- Showerheads and hoses
- Centrally-installed misters, atomizers, air washers, and humidifiers
- Nonsteam aerosol-generating humidifiers
- Eyewash stations
- Ice machines
- Hot tubs/saunas
- Decorative fountains
- Cooling towers
- Medical devices (such as CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units)

**CMS Regulatory Authorities**

Pertinent regulations include, but are not limited to, the following:

42 CFR §482.42 for hospitals:
“The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.”
CMS has identified the following equipment to include in the survey:

- hot & cold water tanks
- water heaters
- water-hammer arrestors
- pipes, valves, and fittings
- expansion tanks
- water filters
- electronic and manual faucets
- aerators
- faucet flow restrictors
- showerheads and hoses
- eyewash stations
- ice machines
- centrally-installed misters, atomizers, air washers, and humidifiers
- non-steam aerosol-generating humidifiers
- hot tubs/saunas
- decorative fountains
- cooling towers
- medical devices (such as CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units)
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42 CFR §483.80 for skilled nursing facilities and nursing facilities:
“The facility must establish and maintain an infection prevention and control program designed
to provide a safe, sanitary, and comfortable environment and to help prevent the development
and transmission of communicable diseases and infections.”

42 CFR §485.635(a)(3)(vi) for critical access hospitals (CAHs):
CAH policies must include: “A system for identifying, reporting, investigating and controlling
infections and communicable diseases of patients and personnel.”

**Expectations for Healthcare Facilities and Surveyors**

CMS expects Medicare certified healthcare facilities to have water management policies and
procedures to reduce the risk of growth and spread of *Legionella* and other opportunistic
pathogens in building water systems. An industry standard\(^1\) calling for the development and
implementation of water management programs in large or complex building water systems to
reduce the risk of legionellosis was published in 2015 by American Society of Heating,
Refrigerating, and Air Conditioning Engineers (ASHRAE). In 2016, the CDC and its partners
developed a toolkit to facilitate implementation of this ASHRAE Standard
(https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html). Environmental, clinical, and
epidemiologic considerations for healthcare facilities are described in this toolkit.

Surveyors will review policies, procedures, and reports documenting water management
implementation results to verify that facilities:

- Conduct a facility risk assessment to identify where *Legionella* and other opportunistic
  waterborne pathogens (*e.g.* *Pseudomonas, Acinetobacter, Burkholderia*
  *Stenotrophomonas*, nontuberculous mycobacteria, and fungi) could grow and spread in
  the facility water system.

- Implement a water management program that considers the ASHRAE industry standard
  and the CDC toolkit, and includes control measures such as physical controls,
  temperature management, disinfectant level control, visual inspections, and
  environmental testing for pathogens.

- Specify testing protocols and acceptable ranges for control measures, and document the
  results of testing and corrective actions taken when control limits are not maintained.

Healthcare facilities are expected to comply with CMS requirements to protect the health and
safety of its patients. Those facilities unable to demonstrate measures to minimize the risk of LD
are at risk of citation for non-compliance with the CMS Conditions of Participation. Accrediting
organizations will be surveying healthcare facilities deemed to participate in Medicare for
compliance with the requirements listed in this memorandum, as well, and will cite non-
compliance accordingly.

• Surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities:

• Conduct a facility risk assessment to identify where Legionella and other opportunistic waterborne pathogens (e.g. Pseudomonas, Acinetobacter, Burkholderia, Stenotrophomonas, nontuberculous mycobacteria, and fungi) could grow and spread in the facility water system.

• Implement a water management program that considers the ASHRAE industry standard and the CDC toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

• Specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.
Contact: For questions or concerns regarding this policy memorandum, please contact Dr. Daniel Schwartz at Daniel.schwartz2@cms.hhs.gov.

Effective Date: Immediately. This guidance should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management
• This is an excellent program but is also a very formidable program for medical facility personnel to implement. It is based upon the CDC toolkit for compliance to ASHRAE 188 standard.

• Currently this requirement applies to only medical facilities that have either over-night or permanent patients. However, may be expanded to all medical facilities in the future.
CDC Water Management Program

June 5, 2017

Version 1.1

Developing a Water Management Program to Reduce Legionella Growth & Spread in Buildings

A PRACTICAL GUIDE TO IMPLEMENTING INDUSTRY STANDARDS
Identifying Buildings at Increased Risk

Survey your building (or property) to determine if you need a water management program to reduce the risk of Legionella growth and spread.

If you answer YES to any of questions 1 through 4, you should have a water management program for that building’s hot and cold water distribution system.

**Healthcare Facilities**

Yes ____ No ____ 1. Is your building a healthcare facility where patients stay overnight or does your building house or treat people who have chronic and acute medical problems or weakened immune systems?

Yes ____ No ____ 2. Does your building primarily house people older than 65 years (like a retirement home or assisted-living facility)?

Yes ____ No ____ 3. Does your building have multiple housing units and a centralized hot water system (like a hotel or high-rise apartment complex)?

Yes ____ No ____ 4. Does your building have more than 10 stories (including basement levels)?
CDC Water Management Program

Elements of a Water Management Program

Developing and maintaining a water management program is a multi-step, continuous process. The key steps, listed here, are explained in more detail throughout the toolkit with the associated step number appearing on the page where the specific step is discussed.
CDC Water Management Program

1. Establish a water management program team
Establish a Water Management Program Team

Certain skills, described in the diagram below, are needed to develop and implement your water management program. These skills would typically be provided by a combination of people, some of whom may have multiple skills (examples shown below).
CDC Water Management Program

1. Establish a water management program team

2. *Describe Your building Water Systems using text*
**Describe Your Building Water Systems Using a Flow Diagram**

**EXAMPLE: BUILDING A**

In addition to developing a written description of your building water systems, you should develop a process flow diagram. Below is an example of a process flow diagram for Building A. Note that this diagram does not need to be as detailed as your building plans. In fact, it’s best if the process flow diagram can be understood easily by all members of your team.
CDC Water Management Program

1. Establish a water management program team
2. Describe Your building Water Systems using text
3. *Identify areas where Legionella could grow & spread and control measures*
CMS has identified the following equipment to include in the survey:

- hot & cold water tanks
- water heaters
- water-hammer arrestors
- pipes, valves, and fittings
- expansion tanks
- water filters
- electronic and manual faucets
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- faucet flow restrictors
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- eyewash stations
- ice machines
- centrally-installed misters, atomizers, air washers, and humidifiers
- non-steam aerosol-generating humidifiers
- hot tubs/saunas
- decorative fountains
- cooling towers
- medical devices (such as CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units)
Identify Areas Where *Legionella* Could Grow & Spread

**EXAMPLE: BUILDING A**

Once you have developed your process flow diagram, identify where potentially hazardous conditions could occur in your building water systems. The below diagram points out locations and types of hazardous conditions you could expect in Building A. Each potentially hazardous condition should be addressed individually with a control point, measure, and limit.
CDC Water Management Program

1. Establish a water management program team
2. Describe Your building Water Systems using text
3. Identify areas where Legionella could grow & spread and control measures & Corrective Actions
Control Measures & Corrective Actions: The Basics

The diagram below shows the process of implementing and monitoring control measures. If you find that a control limit (i.e., temperature levels, disinfectant levels) is not being met, you need to take corrective actions to get conditions back to within an acceptable range. The right side, in yellow, illustrates the routine process of monitoring control measures to make sure they are within limits. The left side, in orange, shows the process of what to do if control measures are found to be outside of their limits.
CDC Water Management Program

1. Establish a water management program team
2. Describe Your building Water Systems using text
3. Identify areas where Legionella could grow & spread and control measures & Corrective Actions

4. Decide where control measures should be applied and how to monitor your control measures
Decide How to Monitor Your Control Measures

**EXAMPLE: BUILDING A**

The diagram below shows which types of monitoring could occur at different locations within Building A’s water system to reduce the risk of growth and spread of Legionella.
CDC Water Management Program

1. Establish a water management program team
2. Describe Your building Water Systems using text
3. Identify areas where Legionella could grow & spread and control measures & Corrective Actions
4. Decide where control measures should be applied and how to monitor your control measures
5. Establish ways to intervene when control limits are not met (corrective actions)
Establish Ways to Intervene When Control Limits Are Not Met

CORRECTIVE ACTION EXAMPLES

Building water systems are dynamic. You should plan for your monitoring results to vary over time and be prepared to apply corrective actions. Corrective actions are taken in response to systems performing outside of control limits. The following are examples of corrective actions.

Example 1—Biofilm growth in the decorative fountain

1. During her weekly inspection of the fountain in the first floor lobby, Michelle Patterson notes that the fountain walls have accumulated a slimy growth.

2. As dictated by her water management program, Michelle immediately shuts off the fountain, drains it to the sanitary sewer, and scrubs it with a detergent recommended by the manufacturer.
CDC Water Management Program

1. Establish a water management program team
2. Describe Your building Water Systems using text
3. Identify areas where Legionella could grow & spread and control measures & Corrective Actions
4. Decide where control measures should be applied and how to monitor your control measures
5. Establish ways to intervene when control limits are not met (corrective actions)

6. **Make sure the program is running as designed & is effective (verification and validation)**
Make Sure the Program Is Running as Designed & Is Effective

Verification: Are we doing what we said we would do?

Your program team should establish procedures to confirm, both initially and on an ongoing basis, that the water management program is being implemented as designed. This step is called "verification." For example, if you said you would test the hot tub daily for chlorine and record and communicate those results, have you been doing that? If you found a problem, did you take the action included in your program?

People should not verify the program activity for which they are responsible. For example, if one person is responsible for maintaining the hot tub and another is responsible for the cooling tower, they could verify each other’s work, not their own.

Validation: Is our program actually working?

Now that you have a water management program, you need to be sure that it is effective. Your program team should establish procedures to confirm, both initially and on an ongoing basis, that the water management program effectively controls the hazardous conditions throughout the building water systems. This step is called "validation."

Environmental testing for Legionella is useful to validate the effectiveness of control measures. The program team should
CDC Water Management Program

1. Establish a water management program team
2. Describe Your building Water Systems using text
3. Identify areas where Legionella could grow & spread and control measures & Corrective Actions
4. Decide where control measures should be applied and how to monitor your control measures
5. Establish ways to intervene when control limits are not met (corrective actions)
6. Make sure the program is running as designed & is effective (validation and verification)

7. **Document & Communicate all the activities of your water management program. (from the initial meeting through PM & other maintenance reports)**
Document & Communicate All the Activities of Your Water Management Program

Documentation

Now that you have done all of the work required to create your water management program, write it down. This information will be important to improve your program and if you or others want to review your records. Your written program should include at least the following:

- Program team, including names, titles, contact information, and roles on the team.
- Building description, including location, age, uses, and occupants and visitors.
- Water system description, including general summary, uses of water, aerosol-generating devices (e.g., hot tubs, decorative fountains, cooling towers), and process flow diagrams.
- Control measures, including points in the system where critical limits can be monitored and where control can be applied.
- Confirmatory procedures, including verification steps to show that the program is being followed as written and validation to show that the program is effective.
- Document collection and transport methods and which lab will perform the testing if environmental testing is conducted.
CDC Water Management Program

1. Few medical facilities have the resources or expertise necessary to follow the CDC toolkit.

2. The most efficient and expedient manner of complying with ASHRAE 188 is to form a partnership with Water Treatment Suppliers.
CDC Water Management Program

The benefits of working with a water treatment supplier are they can help in every step of the process:

• Identify Water Management Team
• Identify all sites needing water management
• Provide most practical (& economical) suggestions for plan compliance
• Provide PM program suggestions for auditing plan conformance
• Provide maintenance to keep water system in compliance.
Future for Hemodialysis Facilities

• NY already has adopted ASHRAE 188-2015 for all medical facilities
• TCEQ meeting
• Partnering with Water Treatment Vendors to ensure compliance to CMS regulations
Future for Hemodialysis Facilities

• NY already has adopted ASHRAE 188-2015 for all medical facilities
• TCEQ meeting
• Partnering with Water Treatment Vendors to ensure compliance to CMS regulations
• References:

CDC Water Management Program Toolkit
www.cdc.gov>lelgionella>downloads>toolkit

CMS Legionella Memorandum
Apic.org/Resource/TimeMceFileManager/Periodical_images/CMS-water-program-Winter2017.pdf