Prevention of Legionellosis Associated with Building Water Systems: Best Practices

William F. McCoy, PhD  Chief Technology Officer, Phigenics, LLC
Learning Objectives:

1. Be able to identify HACCP-Based Water Management
2. Review how *Legionella* infects individuals
3. Understand *Legionella* testing accuracy
4. Learn best practices to limit the risk factors of Legionnaires' Disease in your facility
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WHY?
CDC Recommendation to Facility Managers Involved in Legionellosis Outbreaks

• HACCP-based Water Management Programs should be developed for ongoing hazard analysis and control to prevent further disease cases
• Since 2000, the CDC has advised facility managers involved in legionellosis outbreaks to apply HACCP principles
• Since 2000, there has not been a reoccurrence in any facility that has followed this recommendation.

Used with permission from:
Claressa Lucas, PhD

Centers for Disease Control and Prevention (CDC), Atlanta, GA
Division of Bacterial Diseases
Environmental *Legionella* Isolation and Techniques Evaluation (ELITE) Certification Program Coordinator
Microbiologist involved in most US legionellosis outbreak investigations

June 2013
Conditions Common in Outbreaks

• Lack of familiarity with how water is processed in complex building water systems
• Lack of effective microbiological controls
• Lack of coordinated prevention efforts

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June 2013
http://smartwaterleadership.com/CDC.aspx
Worldwide Best Practice

Water safety in buildings

Edited by: David Curthoys, Jamie Bartrem, Emmanuel Brand, Yves Charlier, Jeni Colbourne, David Drury, John Lee, Benedict Schaeffer and Susanne Suman-Lea

LEGIONELLA and the Prevention of Legionellosis

Edited by: Jamie Bartrem, Yves Charlier, John N. Lee, Kathy Pien and Susanne Suman-Lea

2011 2007
What is the Hazard?

Water Safety Plan

How do we know the hazard has been prevented from hurting people?

How do we prevent the hazard from hurting people?

Assemble Water Safety Plan Team

Describe and document the system

Undertake a hazard assessment and risk characterization

Assess the existing system and produce a process flow diagram

Identify hazard control measures

Define what control limits are necessary for acceptable performance, validate that hazard control has been achieved under operating conditions and establish a monitoring program

Establish procedures to verify that the plan is effectively implemented

Develop supporting programs (training, SOPs, management resp., indep. Surveillance, etc.)

Prepare management procedures including corrective action plan for normal and incident conditions

Establish documentation and communication procedures

Schematic of the HACCP-based Water Management Program as described by the World Health Organization
What is the hazard?

HACCP Water Safety Plan

How do we know the hazard has been prevented from harming people?

How do we prevent the hazard from harming people?
What is the hazard?

HACCP Water Safety Plan

Hazard Control

Validation & Verification

How do we prevent the hazard from harming people?

How do we know the hazard has been prevented from harming people?

Hazard Analysis

How do we prevent the hazard from harming people?
HAZARD ANALYSIS

HAZARD CONTROL

VALIDATION AND VERIFICATION
1. Systematically analyze hazards using process flow diagrams

2. Identify critical control points (CCPs)

3. Establish critical limits for each CCP

4. Establish control and monitoring procedures

5. Establish corrective action procedures

6. Establish record keeping plan, a crisis response plan and assign responsibilities

7. Regularly validate and verify that the HACCP plan is being effectively implemented
VALIDATION AND VERIFICATION

Validation is evidence that hazards have been controlled under operating conditions

*Legionella* test results are useful as validation evidence if precision, accuracy and limit of detection issues are properly considered

Verification is confirmation (documentation) that the HACCP-based Water Management Program has actually been implemented.
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Chest X-rays of a normal healthy individual (top) and a legionellosis patient on admission, day 4, post-infection 1yr and 7yrs. Long-term effects can be seen in the post-infection radiographic images (Bartlett 1986)

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Hundreds of millions of dollars have been spent responding to *Legionella* test results.
Thousands of building water systems are regularly tested for *Legionella* in the U.S.

Tens of millions of building water samples have been analyzed globally since publication of spread plate protocols and an ISO method

And yet, the analytical issues are not well known....
Legionella Sampling and Testing Methods
Legionella colonies growing on BCYE agar in the laboratory

This is the Spread Plate Method

Accuracy and precision of *Legionella* isolation by US laboratories in the ELITE program pilot study

Claressa E. Lucas*, Thomas H. Taylor Jr., Barry S. Fields
Division of Bacterial Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd NE MS G03, Atlanta, GA 30333, USA

Inaccuracy in *Legionella* tests of building water systems due to sample holding time

William F. McCoy*, Erin L. Downes¹, Lesley F. Leonidas, Melissa F. Cain, Daniel L. Sherman, Kevin Chen, Sangeetha Devender, Michael J. Neville²
Phigenics, LLC, 1701 Quincy Ave., Suite 32, Naperville, IL 60540, USA
Precision and Accuracy of *Legionella* Test Results

Only order-of-magnitude numerical values of test results are significant. For example in 121 CFU/ml, the “21” value is not in significant figures. This test result should be simply regarded as $10^2$ CFU/ml.

Results with numerical differences less than one order-of-magnitude are not significantly different.

The practical limit of quantification is 10 CFU *Legionella*/ml. The relevance of far lower theoretical detection limits is in question; recommendations based on numerical values “in the noise” may lead to potentially dangerous actions.

Unpredictable changes in shipped or otherwise held water samples cause inaccurate results that can be eliminated by starting the culture on-site at “time zero”, immediately after the sample is removed from the building water system.
1. GATHER MATERIALS
   One water sample location requires the following items found in the shipping carton:
   - 100mL EPA Vial (Sterile with Neutralizing Tablet)
   - 2 Dipslide Vials (Sterile)
   - 2 Location ID Labels
   - pH Adjust
   - 2 Security Seals
   - 2 Incubators
   - Shipping Label (FedEx 2nd-day Air Return)

   In addition to the supplied items (above) you will need:
   - Safety Glasses
   - Timer (recommended)
   - Gloves
   - Packing Tape

2. AFFIX LOCATION ID LABELS
   Affix completed Location ID Labels horizontally to Dipslide Vials.

3. COLLECT WATER SAMPLE
   IMPORTANT: Safety glasses and gloves must be worn through Step 6 below. Ensure Neutralizing Tablet (sodium thiosulfate) is inside EPA Vial. Fill vial to 100 mL. Fill Line with water from source to be tested. Allow tablet to dissolve completely (2-3 minutes) before proceeding to STEP 4.

4. DIP 1st DIPSIDE
   NOTE: Dipslides & Vial are sterile. Submerge first Dipslide in filled EPA Vial. After 3 seconds, return dipslide to Dipslide Vial. Cap securely.

5. ADD pH ADJUST
   (Acid treatment, avoid contact with skin or eyes.)
   Empty contents of pH Adjust into EPA Vial, close lid. Swirl to mix. Let stand for 5 minutes.

6. DIP 2nd DIPSIDE
   Repeat Step 5 above with the second dipslide in the new acid treated water sample. Upon completion, dispose of EPA vial and water (contents are environmentally safe).

7. APPLY SECURITY SEALS
   Securely cap both Dipslide Vials. Apply Security Seals over side of cap to side of container exactly as shown. Make sure Security Seals do not cover Location ID Labels.

8. ACTIVATE and INSERT INCUBATORS
   Open both outer wrappers to activate an incubator. Look for warmth to confirm activation. If ambient temperature of shipping carton is below 80°F activate a second incubator. Insert Incubator(s) by wedging in foam block corners. Make sure they do not come in contact with vials.

9. REPACK and SHIP on SAME DAY
   For assurance of safety in shipping, repack Dipslide Vials (lids up) in shipping carton foam holders as shown in photo (left). Replace top foam layer securely over contents. Close and seal lid with tape. Apply pre-addressed 2nd-day shipping label.
Phigenics Validation Test (PVT) Analytical Report

Method Used: TimeZero Method

PVT Sample Information
PASL # 10000
Date Inoculated in Field 1/1/2012
Date of Analysis 1/3/2012

Total Heterotrophic Aerobic Bacteria

Total Heterotrophic Aerobic Bacteria
**** 10^4 CFU/mL

Legionella Test Results
L. pneumophila
serogroup 1 7 CFU 70 CFU/mL
L. pneumophila
serogroups 2-14 0 CFU <10 CFU/mL
Legionella species 0 CFU <10 CFU/mL

Growth media for viable total heterotrophic aerobic bacteria.
Growth media plus antibiotics to suppress non-Legionella bacteria.

(+ ) indicates presence of antibiotics. Dipside received intact. Colonies tested positive for Legionella (as shown above).

Sink #1 Hot
Acid Treated? Y
Date of Testing 01/01/12
Signature of Collector

Joe Smith

Analyst Signature
Sergio Roldan
Date 1/3/2012

Reviewer Signature
Hilton L. Goy
Date 1/3/2012

Disclaimer: Results from the PVT, or from any other analytical protocol for that matter, do not necessarily provide enough evidence to ensure that hazards from pathogenic microorganisms have been eliminated or controlled nor that risk of harm from such hazards has been reduced. Results from the PVT should only be interpreted within the context of properly designed and implemented water management plans. No guarantee regarding results is expressed or implied. THE PVT AND THE RESULTS IT PRODUCES ARE PROVIDED ON AN “AS IS” BASIS. YOU ASSUME TOTAL RESPONSIBILITY AND RISK FOR YOUR USE OF THE PVT AND PHIGENICS IS NEITHER RESPONSIBLE NOR LIABLE FOR ANY DAMAGES ARISING OUT OF YOUR USE OF THE PVT.

Phigenics Analytical Services Laboratory
1701 Quincy Avenue, Suite 32
Phone: 830-717-7546
Fax: 830-717-8528

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Benefits of the PVT
Compared to the Spread Plate Methods for Total Bacteria and for *Legionella*, the PVT is:

- MORE ACCURATE - water samples are not spoiled during shipment to the lab (data is obtained for the exact time the PVT field sampler contacts the water)

- FASTER - transit time is not wasted and micro-colonies are enumerated directly on the PVT field samplers (shipment of samples to laboratory is not required; turnaround time reduced more than 80% compared to ISO Spread Plate Methods)

- MORE COMPREHENSIVE - results for total bacteria AND *Legionella* bacteria are obtained and archived by the Phigenics Analytical Services Laboratory in a standardized protocol for your future reference
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HACCP-based Water Management Programs

Require facility managers/owners to establish a team with assigned responsibilities and accountabilities.

The first job for the team is to describe how water is processed and used in the facility. This description must be schematically represented in process flow diagrams, with each processing step named and numbered on the diagrams.
Next, the team is required to perform **systematic hazard analysis** to:

1) Identify the potential hazards for each step in the process

2) Decide if the risks of those hazards are significant (Yes or No) and if “Yes”,

3) Determine what hazard control is being applied, or should be applied, at that processing step,

4) Designate each processing step at which hazard control is applied a **Critical Control Point (CCP)**.
For each critical control point, the team must address four issues about the hazard control used:

1) The critical control limit(s)
2) The hazard control monitoring method(s),
3) The frequency of hazard control monitoring,
4) The corrective actions to be taken if critical control limits are violated.
Reference: Adapted from content presented by Dale Kragenschmidt at AIHce 2012
Example: Multiple Campus Hospital Water Management Team

- Executive Director
- Director
- Infection Control/Epidemiology
- Environment Risk Manager/Safety Officer
- Facilities Manager/Supervisor
- Facility Engineer - Campus 1
- Facility Engineer - Campus 2
- Facilitator/Consultant
Process Flow Diagrams
1. RECEIVING

2. CONDITIONING

- Potable Water (Distributed from Water Plant)
- Water Softening (Remove Hardness)
- Pre-heat water to raise temperature and remove oxygen
- Water Treatment to Remove Oxygen and Prevent Corrosion

3. HEATING

4. COOLING

- Chilled Water Production (Heat Exchangers)
- Convert (Heat) Feedwater to Steam (Fire-Tube Boiler)
- Cooling Towers for Heat Rejection and Water Conservation
- Condensate Tank (to recapture and re-use steam)
- Sewer (periodic blowdown)

5. DISTRIBUTION

6. WASTE

- Steam Usage for Kitchen, etc.
- Steam Usage for Radiant Heat

CCP
Hazard Analysis Summary

Water Management Plan: Franklin Power Plant

<table>
<thead>
<tr>
<th>Processing Steps</th>
<th>Potential Hazard</th>
<th>Risk Significance?</th>
<th>Risk Basis</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Receiving</td>
<td></td>
<td>NO</td>
<td>Low risk: Water is received from both wells and the City of Rochester. The Rochester Community Public Water Supply is treated to US Standards for drinking water given in the Code of Federal Regulations. Additionally, the Mayo Clinic Franklin Power Plant staff is a permitted Public Water Supply through the state of Minnesota. Both sources of incoming water are highly regulated with specific controls defined. The total source water is controlled via downstream processes. The fire suppression system is filled with City of Rochester water. Though there is potential for microbiological growth due to stagnant lines, the system is also categorized as low risk due to very limited exposure potential.</td>
<td>1. Obtain product from sources that are certified to the National Drinking Water Regulations (NDWR) 2. Obtain water quality test results from the municipal water provider every six months 3. Comply with all public water supply permit requirements for the well-source water. 4. For fire suppression system, perform testing per code requirements and wear PPE for annual flush testing.</td>
</tr>
</tbody>
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**Legionella HAZARD CONTROL**

**Utility Water**
- Water Preconditioning
  - Filtration
  - Softening

**Potable Water**
- Thermal Disinfection and Flushing
- EPA-Approved Secondary Disinfection
  - Chlorine
  - Chloramines
  - Chlorine dioxide

**Scale and Corrosion Inhibition**

**EPA-Registered Biocides**
- Oxidizing biocides
- Non-oxidizing biocides

**Other Treatments**
- Point-of-Use Filtration
- Cu/Ag Ionization
- Ozone
- UV Disinfection

**Dispersants**
Corrective Actions

Procedure followed if there is a deviation from the critical limit.

Every CCP must have a specified critical limit and a monitoring plan for the critical limit.

Every critical limit must have a corrective action specified.
Independent Data Management, Verification and Validation

A few comments about the importance of defensible data management, verification and validation

• If there are no defensible records documenting that something was done, then from a defensibility perspective, that something was not done.

• Conflict of interest allegations are hard to defend against unless provisions are made to establish some degree of independence

• Eliminate “the fox is watching the hen-house” scenario with regard to hazard control treatment and other service providers.
Welcome to phiMetrics

- Enter Data
- View Data
- Charts
- PVT Reports
- Management Dashboard
- Alerts
Management Dashboard

% Legionella Positive

% Legionella Positive >100 CFU/mL

% Legionella Positive >1000 CFU/mL

% THAB Samples >10^4 CFU/mL

Total Samples Analyzed

Location: Cooling Tower
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<thead>
<tr>
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<th>PASL #</th>
<th>Method</th>
<th>Date Inoculated</th>
<th>Date Analyzed</th>
<th>Collector</th>
<th>Location</th>
<th>Type</th>
<th>THAB</th>
<th>Negative Screen</th>
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<td>1/5/2010</td>
<td>1/5/2010</td>
<td>N. Shah</td>
<td>PCT 3</td>
<td>Utility</td>
<td>10^6</td>
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<td>&lt;10</td>
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Regulatory
Section I: What is Legionnaires' disease?

Legionnaires' disease is a common name for one of the several illnesses caused by Legionnaires' disease bacteria (LDB). Legionnaires' disease is an infection of the lungs and is a form of pneumonia. More than 43 species of *Legionella* have been identified and more than 20 linked with human diseases. *Legionellosis* is the term for the diseases produced by LDB. In addition to Legionnaires' disease, the same bacteria also cause a flu-like disease called Pontiac fever.

- Legionnaires' disease bacteria (LDB)
  - What are LDB?
  - What are the sources of exposure and transmission?
- Legionnaires' disease/Pontiac fever
  - What are the symptoms?
  - What are the incidence rates and risk factors?
  - How is Legionnaires' disease diagnosed and treated?
OSHA

Section 5(a)(1) of the OSH Act, often referred to as the General Duty Clause, requires employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees". The General Duty Clause covers failures to follow recognized good industry practices for instances in which Legionnaires' disease has been linked to poorly maintained water systems. Section 5(a)(2) requires employers to "comply with occupational safety and health standards promulgated under this Act".

Note: Twenty-four states, Puerto Rico and the Virgin Islands have OSHA-approved State Plans and have adopted their own standards and enforcement policies. For the most part, these States adopt standards that are identical to Federal OSHA. However, some States have adopted different standards applicable to this topic or may have different enforcement policies.

Federal Registers

- Search all available Federal Registers.

Directives

  - Legionnaires' Disease. Provides information to assist industrial hygienists in the assessment of work sites for potential Legionnaires' disease, disease recognition, investigation procedures to identify probable water sources, and control strategies.
  - Legionnaires' Disease. eTool. Offers a graphical menu to assist in the assessment of worksites for potential Legionnaires' disease and provides information on disease recognition, investigation procedures, and control strategies.
- Search all available directives.
CONCLUSIONS

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