

Using HACCP Water Management Plans to Prevent Legionellosis in Healthcare Facilities

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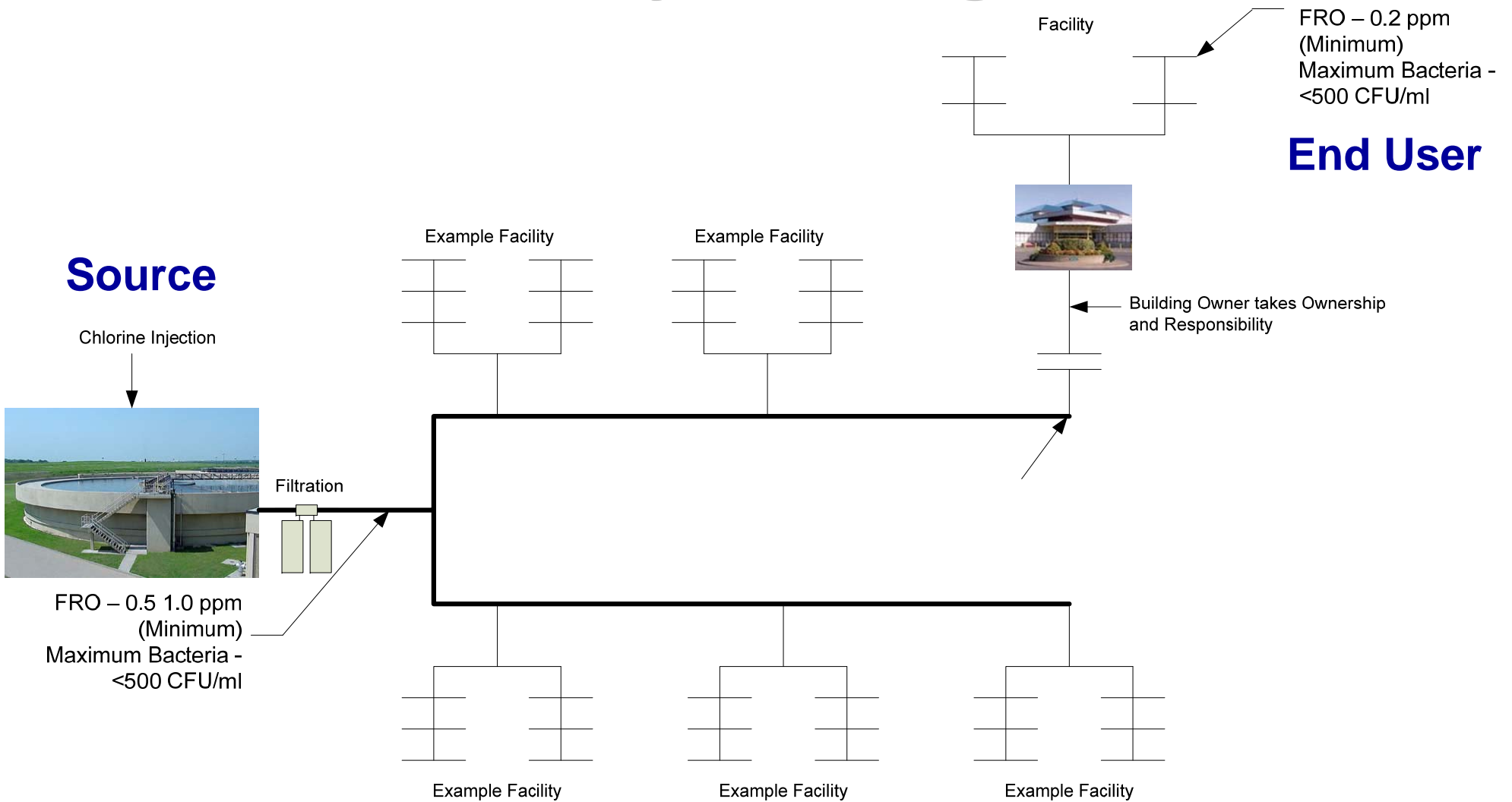
Melissa Cain

Phigenics, LLC

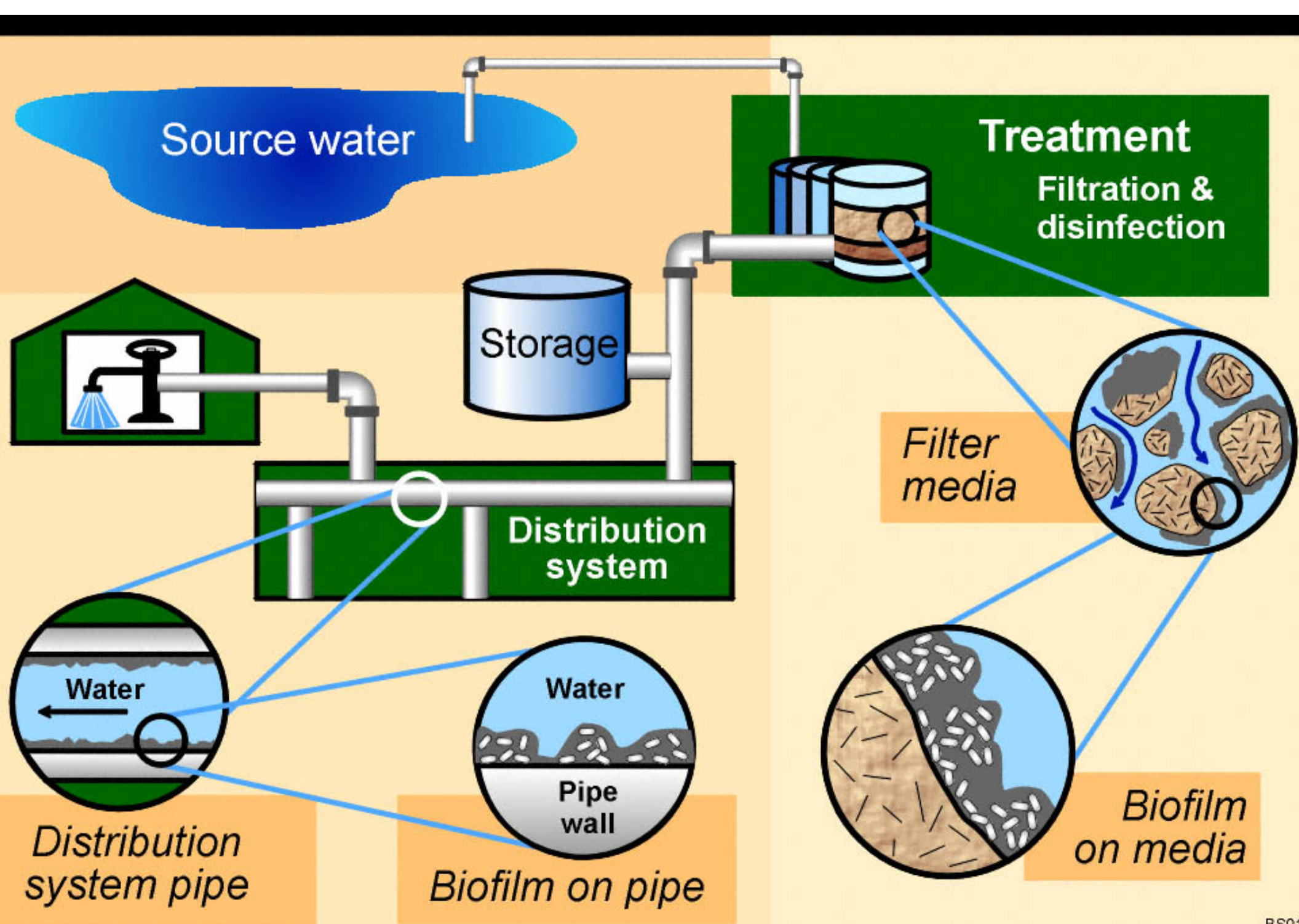
**How Do Building Water Systems
Become Unsafe?**

How Can Water Quality Degrade?

Water Quality: The Big Picture



Goal: To maintain water quality or improve it compared to how it was received



The Distribution System as Reactor

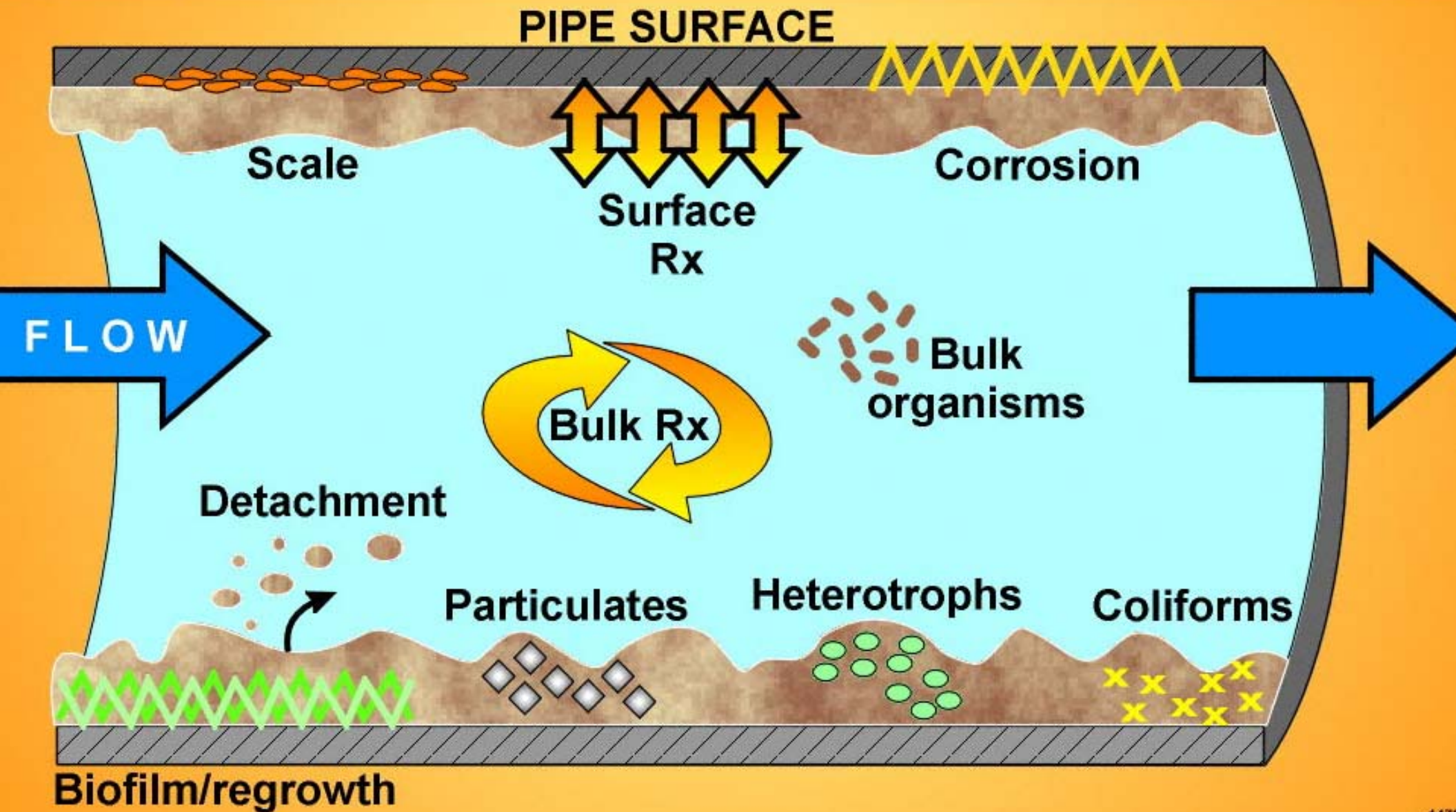
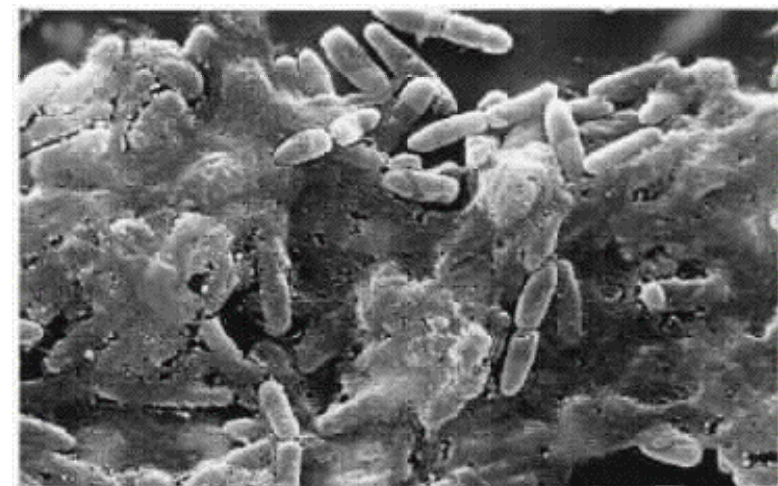




Figure 2. Left: Tubercle formation in a carbon steel fire protection pipe. Iron oxidizing bacteria were found in association with the tubercles. Right: Bacterial biofilm associated with stainless steel tube. Scanning electron micrograph magnification at 5,000X (Mittelman, 2001).



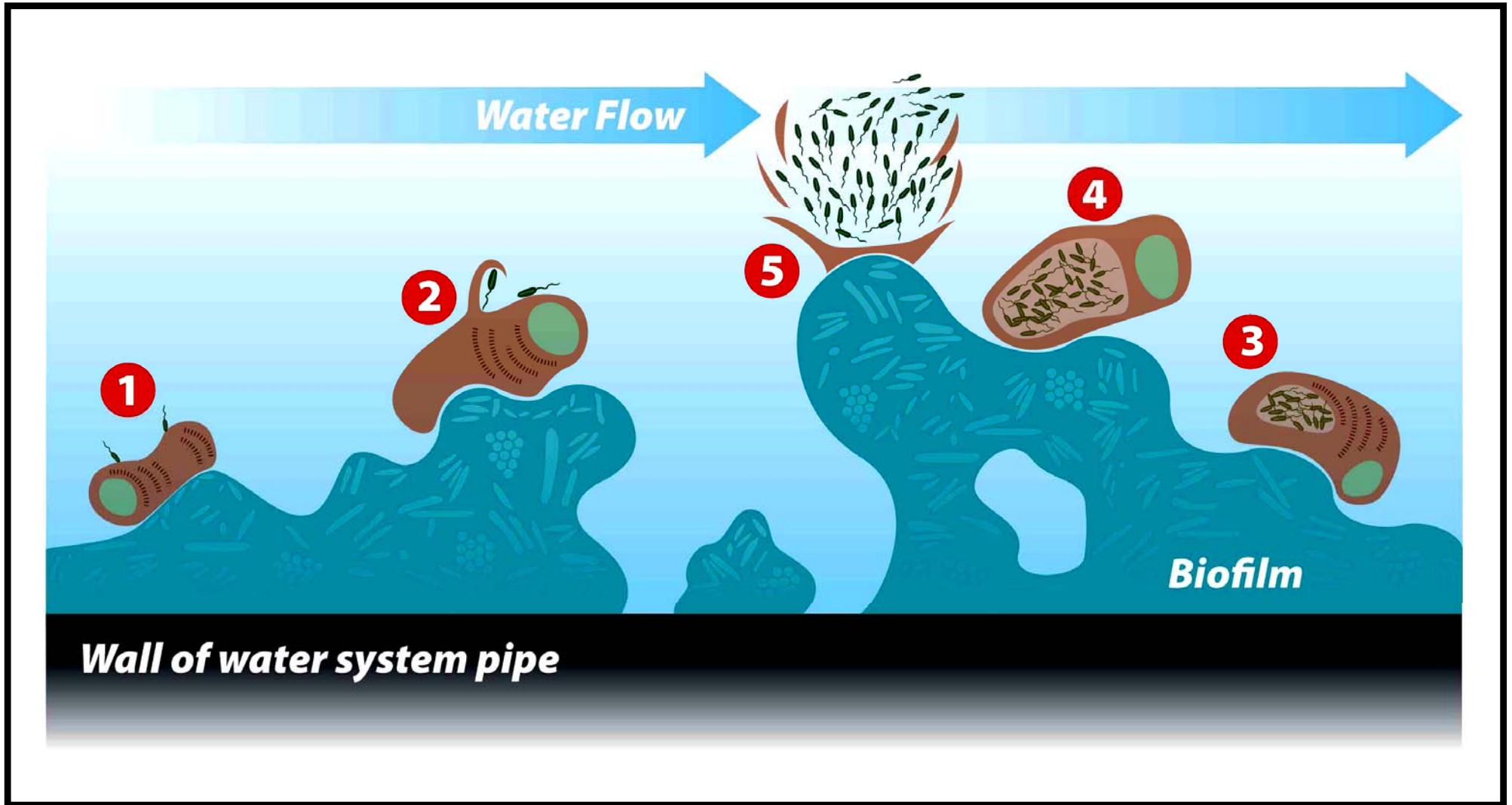
*Figure 3. Electron micrograph of interior surface of a vascular catheter removed from a patient showing growth of a bacterial biofilm of *P. aeruginosa*. (Yassien et al., 1995). Biofilm bacteria leaving the catheter can cause sepsis.*

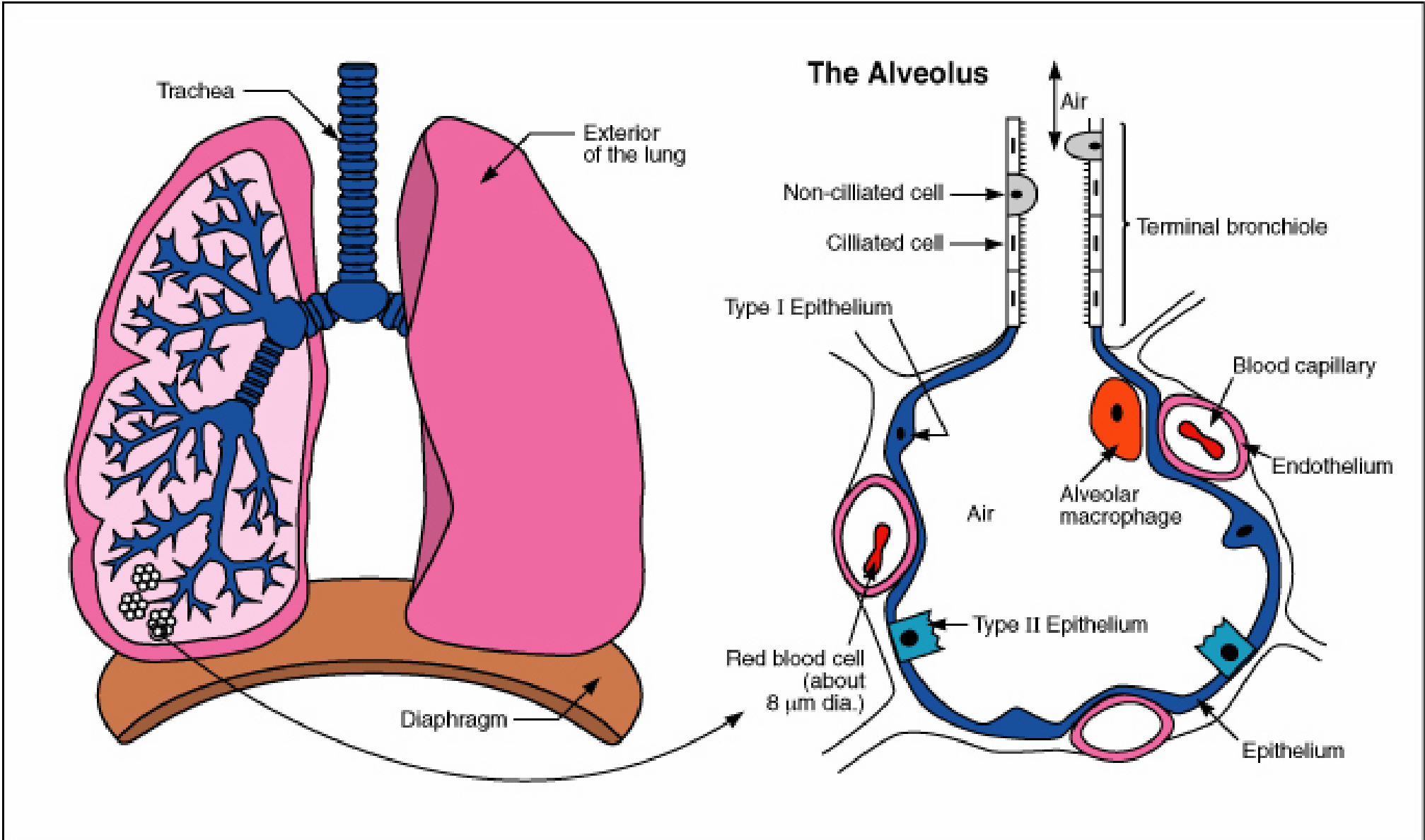
**Significance of *Legionella*:
Potential for Exponential Growth**

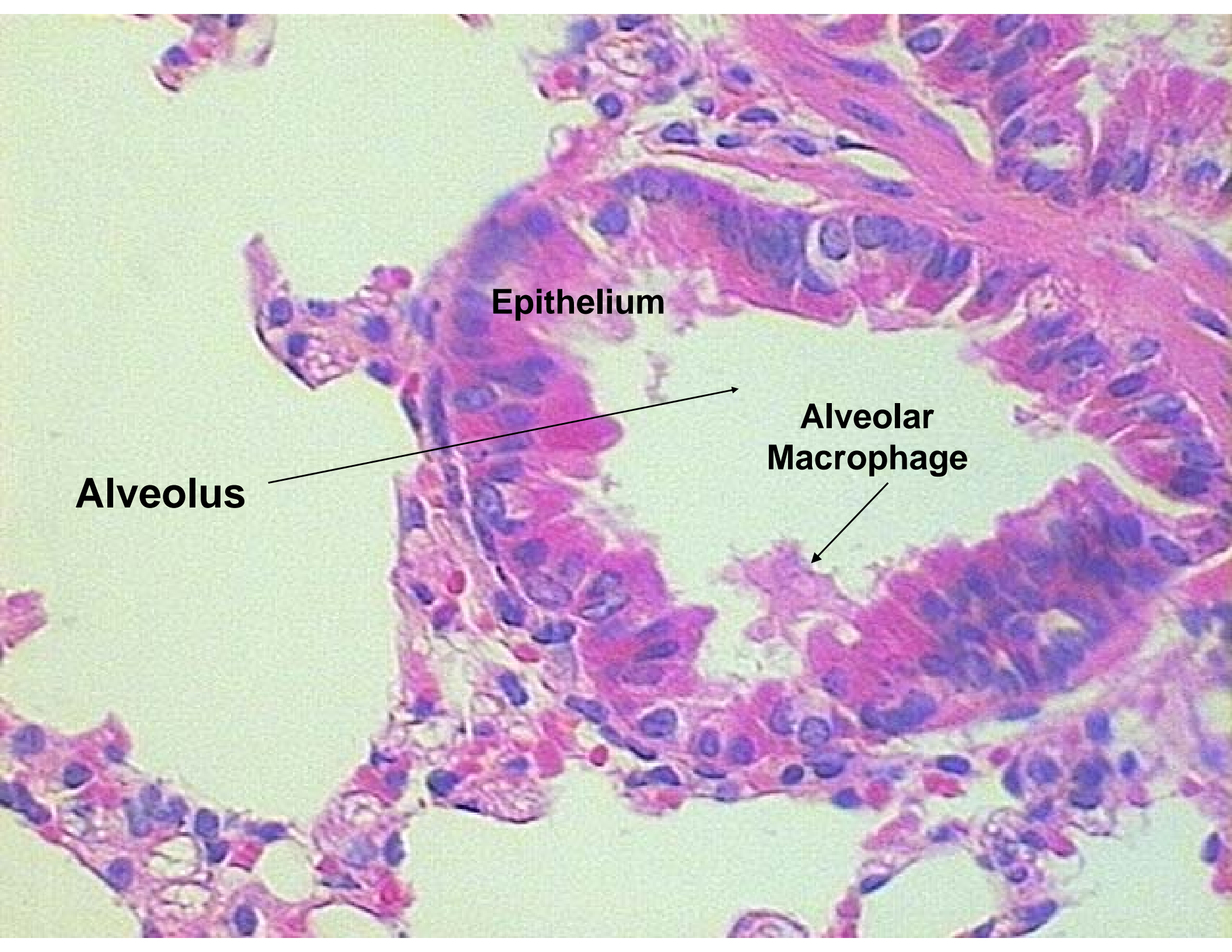
Legionnaires' Disease

(Legionellosis, or *Legionella*-caused pneumonia):

The Disease and Effects



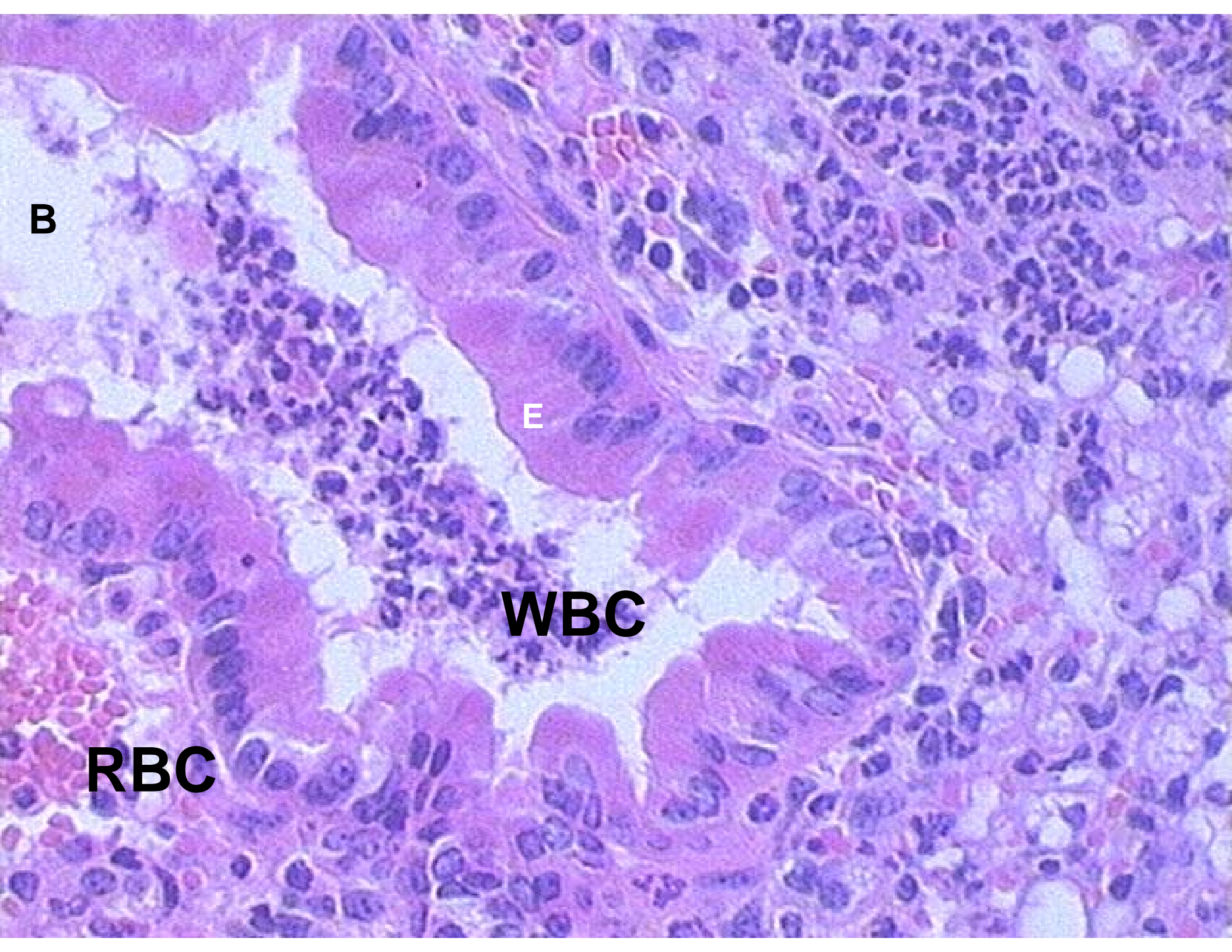




Epithelium

**Alveolar
Macrophage**

Alveolus



B

E

WBC

RBC

Intracellular Growth

2nd movie : *Lp* inside amoeba

10-16 h after gentamicine removing
(14-20h incubation)

Approx. $3 \cdot 10^7$ CFU/mL

Lysis and Reinfection

3rd movie : amoebal lysis

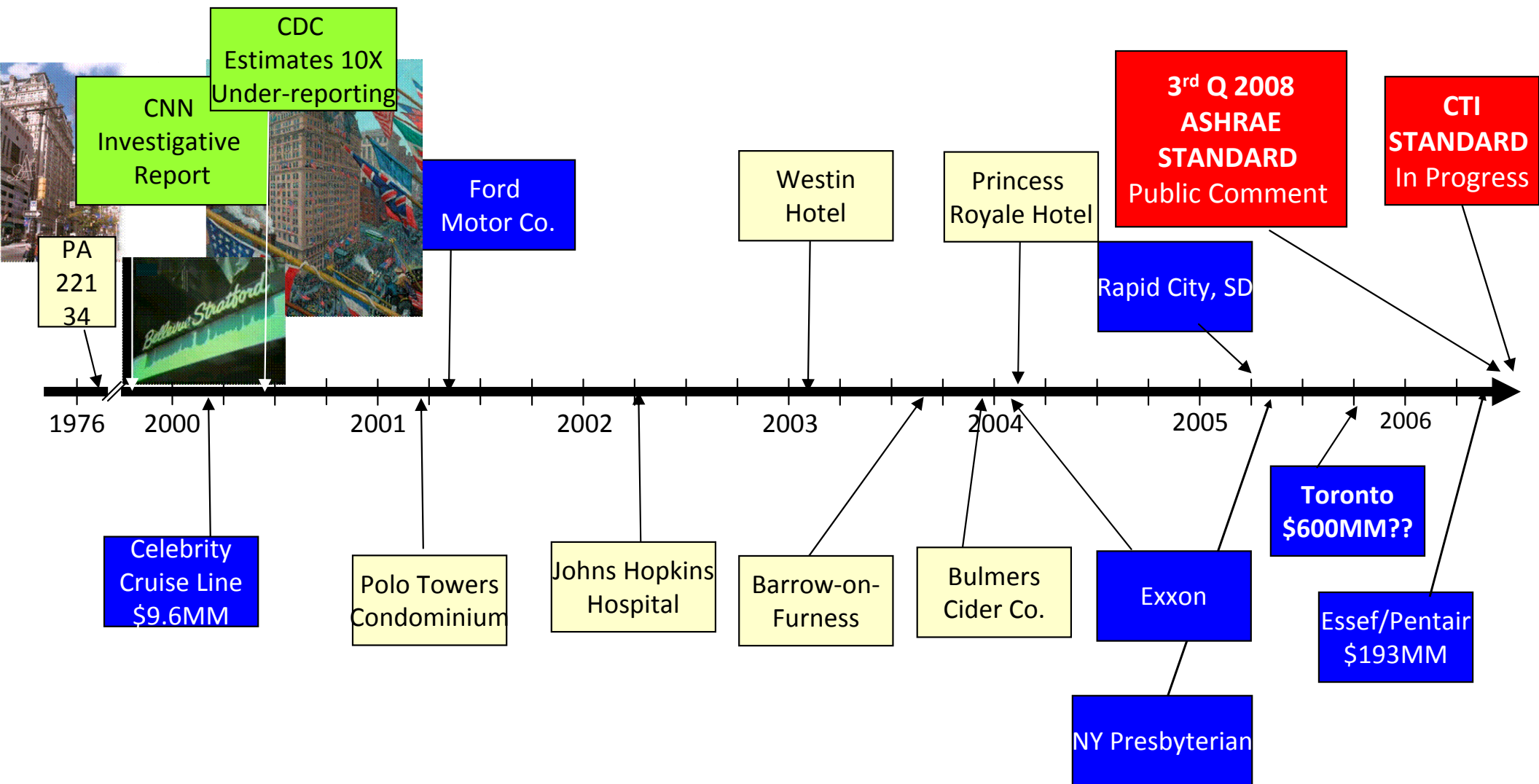
20h after gentamicine removing
(24h incubation)

Approx. 10^8 CFU/mL

Reported Legionellosis Cases

Industry Response

Cases of Legionnaires' Disease (legionellosis) Motivating Lawsuits and U.S. Standards Development



What is Common to these Cases and Events?

- Extensive Brand Damage
- High Cost of Litigation and/or Settlement
- Significant Cost to Operations (emergency remediation, capital equipment purchases, water service interruptions, etc.)
- Industry Actions Indicate Responsibility Lies with Facility Owners
- These Cases Are *Preventable*

Industry Guidance, Regulations and Standards

How Can Disease Be Prevented?

Legionellosis

Guideline: Best Practices for Control of Legionella



State of Maryland

Department of Health & Mental Hygiene

Blending, Governor • Kathleen Kennedy Townsend, Lt. Governor
• Georges C. Benjamin, M.D., Secretary

Report of the Maryland Scientific Working Group to
Study Legionella in Water Systems in Healthcare Institutions

June 14, 2000
Baltimore, Maryland

APPROACHES TO PREVENTION AND CONTROL OF LEGIONELLA INFECTION IN ALLEGHENY COUNTY HEALTH CARE FACILITIES



Occupational Safety & Health Administration
U.S. Department of Labor

[Technical Links](#) > [Osha Technical Manual](#)

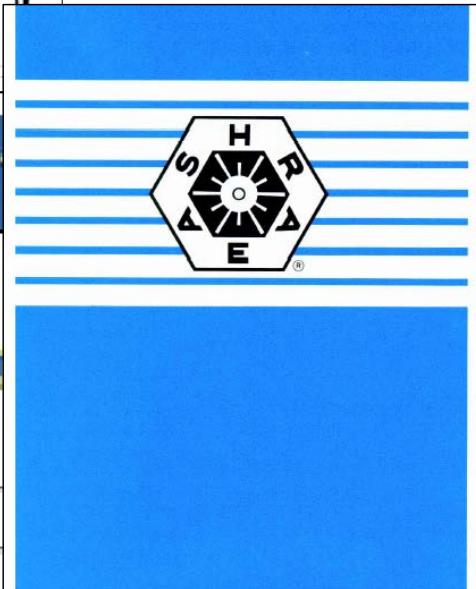
OSHA Technical Manual

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SECTION III: CHAPTER 7
LEGIONNAIRES' DISEASE

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- I. [Introduction](#)
- II. [Disease Recognition](#)
- III. [Source Identification](#)
- IV. [Investigation Protocol](#)
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ASHRAE Guideline 12-2000

ASHRAE STANDARD

Minimizing the Risk of
Legionellosis Associated
with Building Water
Systems

Centers for Disease Control and Prevention
Healthcare Infection Control Practices Advisory Committee (HICPAC)

Draft Guideline for Environmental Infection Control in
Healthcare Facilities, 2001

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Current Regulations: OSHA General Duty Clause



U.S. Department of Labor
Occupational Safety & Health Administration



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Legionnaires' Disease Standards

There are currently no specific OSHA standards for Legionnaires' disease. This page highlights OSHA Federal Registers (rules, proposed rules, and notices), directives (instructions for compliance officers), and national consensus standards related to Legionnaires' disease.

OSHA

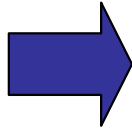
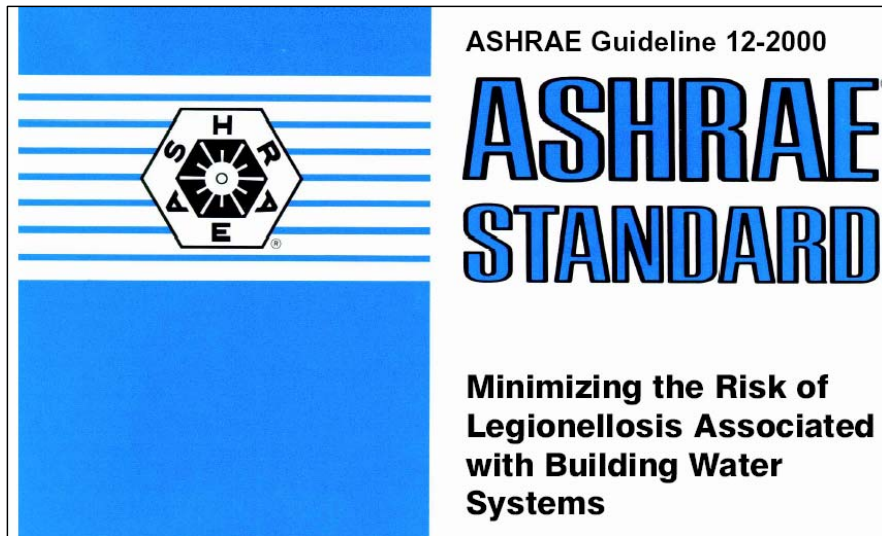
[Section 5\(a\)\(1\)](#) of the OSH Act, often referred to as the General Duty Clause, requires employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees". 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".

The Joint Commission

Environment of Care Standard EC 7.10

- EC 7.10 Rationale
 - Establish and maintain a utility systems management program to promote a safe, controlled and comfortable environment that... reduces the potential for hospital-acquired illness to be transmitted through the utility systems
- EC 7.10 Elements of Performance, B 15:
 - Healthcare Facility identifies and implements processes to minimize pathogenic biological agents in cooling towers, domestic hot/cold water systems and aerosolizing water systems.

Forthcoming - ASHRAE Standard SPC188



In Working Draft Phase
STANDARD SPC188
Prevention of Legionellosis
Associated with Building
Water Systems

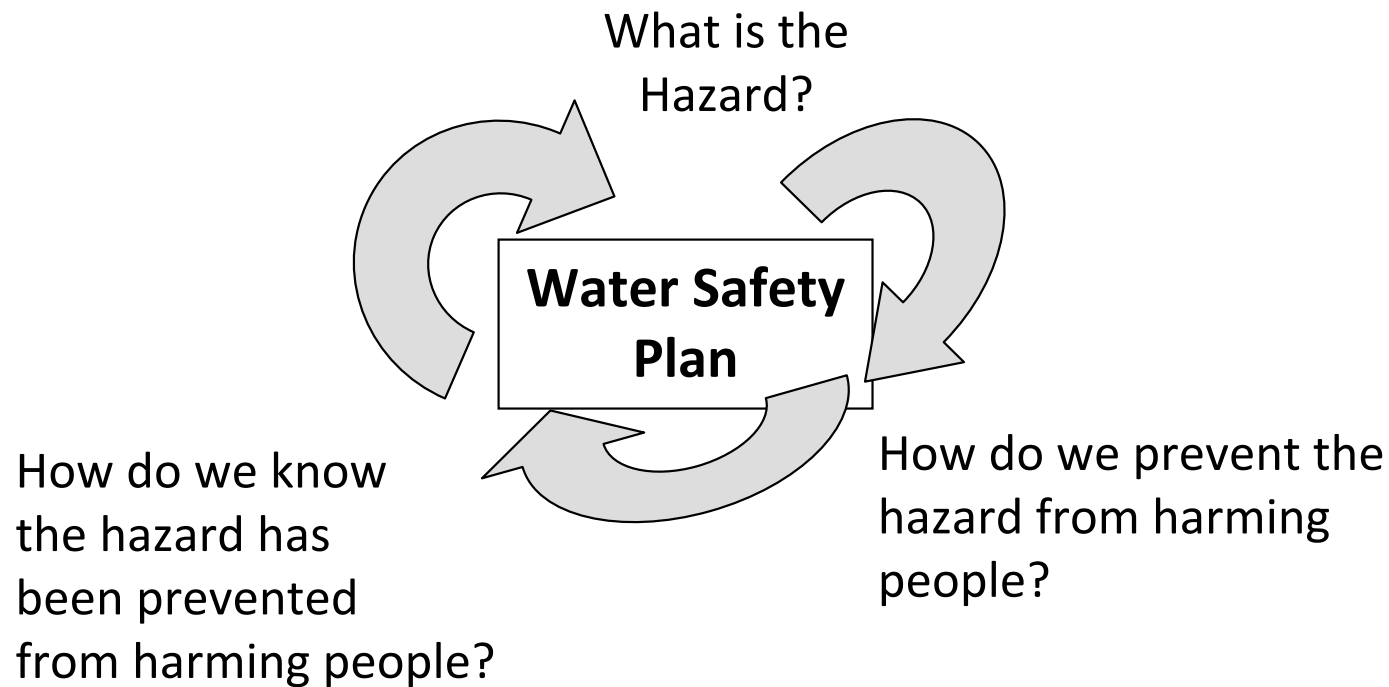
WHAT WILL BE CHANGING IN THE STANDARD?

Utilize the Hazard Analysis Critical Control Point (HACCP) Process:

Need a *systematic, risk management plan* to establish and document the decision-making process.

Validation, independent, quantitative evidence, that the water system is free of hazards or they have been prevented from harming people.

HACCP Must Be Simple, Effective and Sustainable



HACCP Plans: Providing Due Diligence

- Proven successful in prevention of foodborne and waterborne illness
- What do HACCP Plans provide?
 - Prevention of “reasonably foreseeable harm” and demonstration of compliance with statutory obligations
 - Can be applied in preventative sense to mitigate water contamination (*i.e.*, hazards)
 - Can be used to manage specific cases of contamination or lack of control measures to prevent harm
 - *i.e.*, Demonstrate due diligence in the event of a lawsuit or charge of negligence

Hazard Analysis Critical Control Point (HACCP) System

Water Management Plan

The 5 Preliminary Steps of HACCP

1. Assemble a HACCP team that includes 1 HACCP trained person (e.g., a certified HACCP manager/consultant or trained employee)
2. Identify end users of the water, especially to determine at-risk consumers
3. Identify all uses for the water at the facility
4. Develop process flow diagrams to determine how the water is processed in the facility
5. Verify that process flow diagrams are accurate by on-site confirmation

The 7 Principles of HACCP

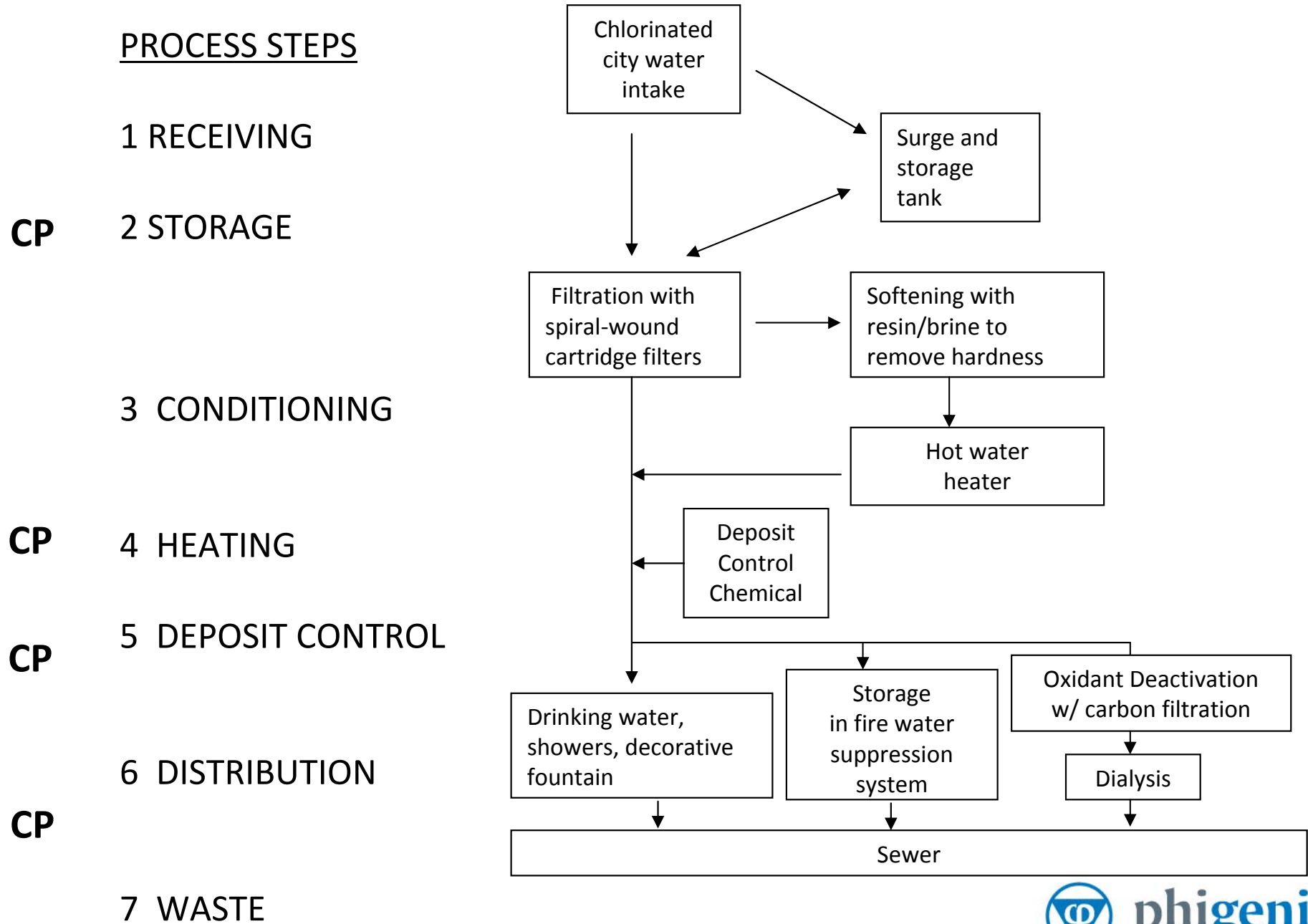
1. Systematically analyze hazards using process flow diagrams
2. Identify critical control points (CCPs)
3. Establish critical limits for each CCP

Critical Control Point

be Last step in the water process at which controlled can
applied to eliminate, control or prevent hazards from
causing harm

and Step in the process at which the most cost-effective
operational feasible hazard control can be applied

PROCESS CATEGORY: INSTITUTIONAL FACILITY WATER SYSTEM
PRODUCT: POTABLE WATER



PROCESS CATEGORY: INSTITUTIONAL FACILITY WATER SYSTEM
PRODUCT: POTABLE WATER

PROCESS STEPS

1 RECEIVING

2 STORAGE

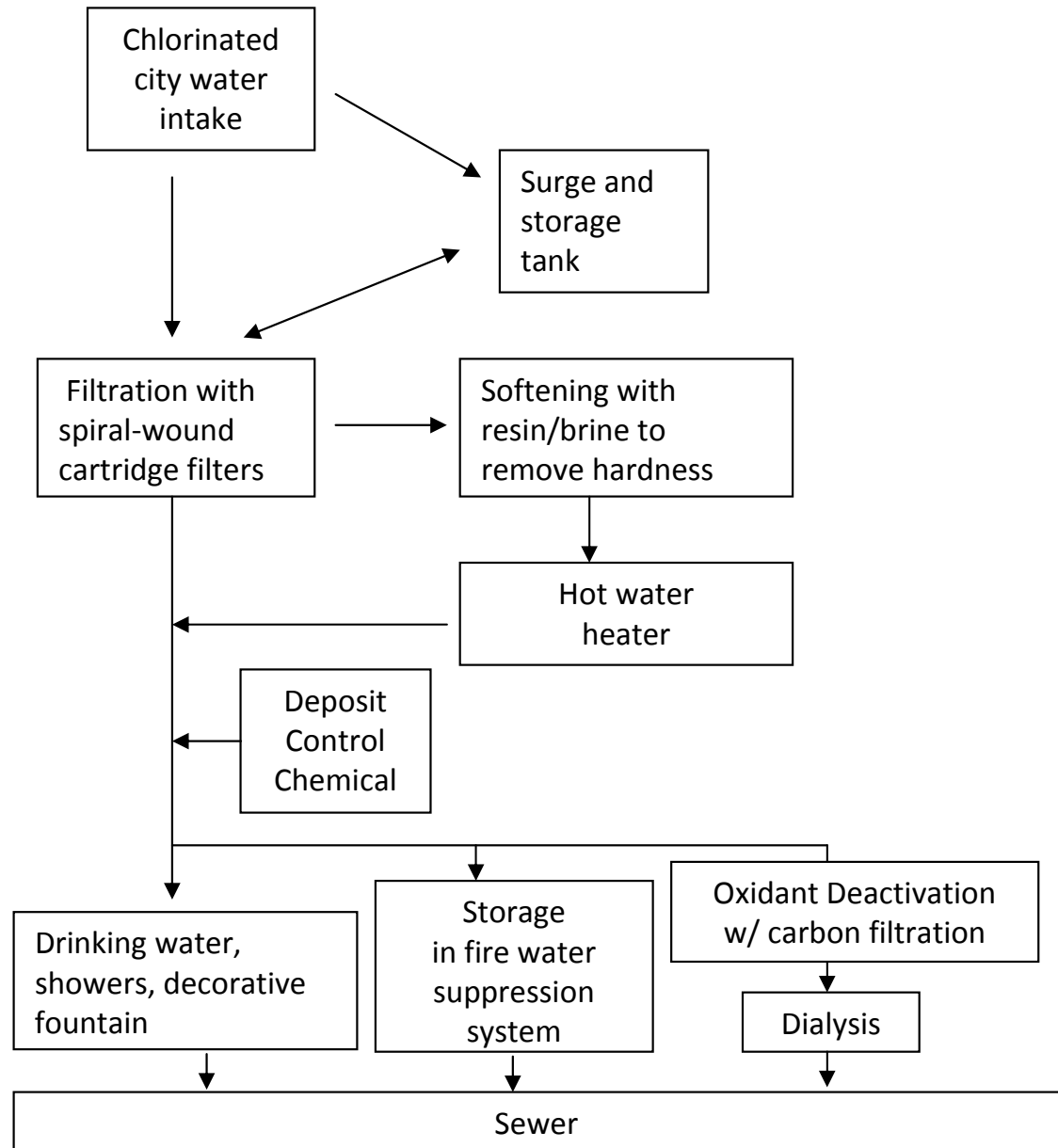
3 CONDITIONING

CCP 4 HEATING

CCP 5 DEPOSIT CONTROL

6 DISTRIBUTION

7 WASTE



The 7 Principles of HACCP

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

Quantitative evidence (data) that control limits have prevented, eliminated or reduced the hazard under operating conditions

Verification

Independent confirmation that the risk management plan is being implemented correctly and is periodically reassessed

Validation Criteria

Validation criteria must be established on a site-by-site basis as part of the Water Management Plan.

Typically in well-managed **potable water systems**, the total viable heterotrophic aerobic bacterial concentration will be less than 500 CFU/ml and the viable *Legionella* bacteria concentration will be less than 10 CFU/ml.

Typically in well-managed **utility water systems** (such as cooling water towers), the total viable heterotrophic aerobic bacterial concentration will be less than 10,000 CFU/ml and the viable *Legionella* concentration will be less than 10 CFU/ml.

OSHA Recommendations

Interpretation Guidelines:

- The OSHA suggested guideline for LDB in domestic hot- and tepid-water systems is less than 10 CFU per milliliter.

Interpretation Guidelines:

- The OSHA suggested guideline for LDB in domestic cold-water systems is less than 10 CFU per milliliter.

COOLING TECHNOLOGY INSTITUTE

March 2006

CTI Guidelines WTP-148 (06)

Legionellosis

Guideline: Best Practices for Control of Legionella




Recommended Target Values Routine Treatment of Cooling Water Systems

Parameter	Dipslides	Agar Pour Plate or Petrifilm	Microscopic Exam
Planktonic Counts (Bulk Water)	<10,000 CFU/mL	<10,000 CFU/mL	No higher life forms
Sessile Counts (Surfaces)	<100,000 CFU/cm ²	<100,000 CFU/cm ²	No higher life forms
Deposits	NA	NA	No higher life forms

Implementation

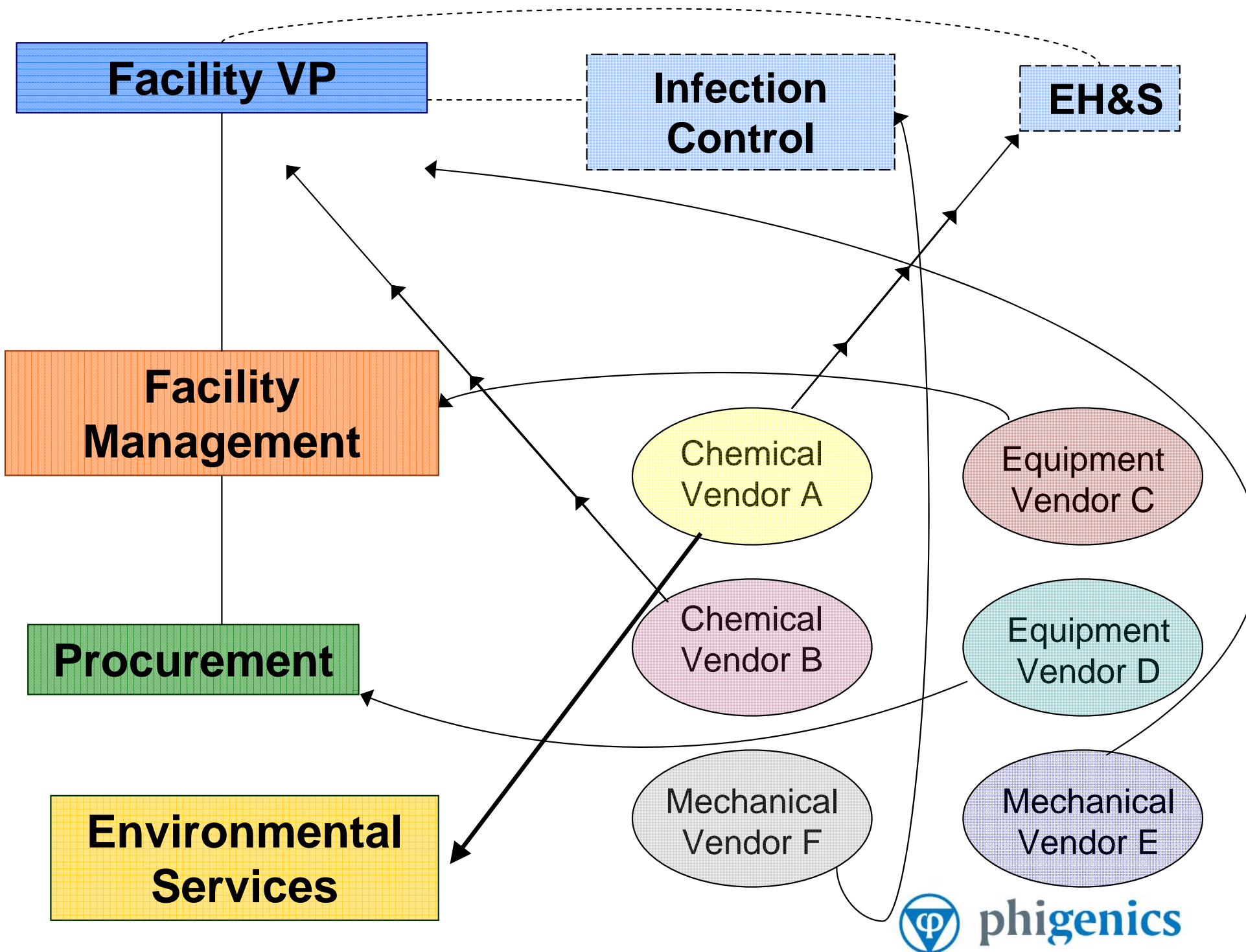
Supporting Documents And The HACCP Plan For A Facility Water System

Documents	Description	Purpose
Process Flow Diagrams (The potable water and utility water)	Simple schematics to show how water is processed in the facility. Water in every facility is processed for utilities and for domestic (potable) service. Examples of water-processing steps are conditioning, softening, filtering, storage, cooling, heating, distribution, cleaning, disinfecting, etc.	Identifies the products (utility water or potable water) and the processing steps used to prepare water for use in the utilities (<i>e.g.</i> , the boilers, cooling towers, fire-suppression systems) and for use or consumption by building occupants (<i>e.g.</i> , cooking, drinking, bathing, showering, etc).
Hazard Analysis Summaries	Systematic list of hazards for each processing step. Indicates the severity/risk of each hazard. Lists the specific control measures that could be applied to prevent, eliminate or reduce the hazard.	Identifies critical control points (CCPs) for the process. Typically, there will be one or two CCP for each process.
Validation Criteria	Lists the specific quantitative measurement criteria for each hazard or for performance criteria directly related to the hazard	Evidence (data) to confirm that the hazard has been eliminated, reduced to acceptable levels or prevented under operating conditions from harming people.
Validation and Verification Schedule	Systematic list of required activities, frequencies, responsibilities, the review schedule and the dates. Assignment of responsibilities and accountability is critical to successful implementation of HACCP plans	Coordinates activity to obtain data proving that the plan actually works (validation) and that the plan is being properly implemented (verification). Coordinates documentation of control limit monitoring and corrective action reports.
The HACCP Plan Document	Lists the specific control limit for each CCP, the monitoring frequency, the corrective action required if a critical limit has been breached, reporting responsibilities and	Provides details of the entire plan in one document. During a HACCP audit, this is the key document for review. 

HACCP Case Study: Healthcare Facility Water Management Plan

Healthcare Facility Background

- Multi-Hospital Network in Chicago area
- Historical use of hazard control solution (copper-silver ionization system) for waterborne pathogen control
- Performs periodic *Legionella* testing
- Several “water-related” suppliers (chemicals and equipment)
- Many hospital departments with shared interest of water safety and cost-efficiency
- Various roles, responsibilities and communication across departments



Water Management Plan: Scope of Work

- Align processes and procedures across all locations
- Design HACCP Water Management Plan for all facilities
 - Define Critical Control Points
 - Define Corrective Action procedures
 - Define Validation testing strategy
- Document Decision-Making and align with current/forthcoming regulatory drivers
- Implement efficient record-keeping system for executive communications

Water Management Plan: Achievements

- Formation of Water Management Team
 - Establishes consistent practices and documentation across the healthcare organization.
 - Brings key functional areas/departments to the table and facilitates discussion around all aspects of potable and utility water processes.
 - Defines process to manage water-related suppliers
 - Acts as a resource to executive management to support strategic decision-making regarding the safety and operations of all water systems.

Water Management Plan: Achievements

- Completion of Process Flow Diagrams
 - Systematically described water processes across all three locations
 - Team identified additional uses of diagrams outside of proactive Water Management
 - Emergency Management
 - Cost-Optimization/Savings Opportunities
- Hazard Analysis Summary
 - Documented Risk Characterization Levels
 - Selection of Critical Control Points within water system process

Process Flow Diagram:

Water Management Plan: Achievements

- Documentation of Hazard Control Strategies
 - Existing control methods
 - Additional control and monitoring
 - Corrective action strategies
- Definition of Validation & Verification Strategy
 - *Legionella* testing strategy
 - Continual Plan is being followed and is effective.
- Record-Keeping Plan
 - Defensibility through documented rationale
 - Concise documentation for executive committees

Water Management Q&A