PREVENTION OF HEALTH CARE-ASSOCIATED *LEGIONELLA* DISEASE AND SCALD INJURY FROM WATER SYSTEMS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive addresses the prevention of health care-associated *Legionella* disease and scald injury from water systems in VHA buildings in which patients, residents or visitors stay overnight; in VHA buildings where employees are required to sleep overnight; and for the management of select outdoor non-potable water systems.

2. SUMMARY OF MAJOR CHANGES:

Amendment dated September 26, 2022:

a. Updates link in paragraph 2.f. Background and 5.j.(10) Responsibilities.

b. Removes outdated and redundant links in paragraph 5.d.(3) and 5h.(3).(a).

c. Clarifies paragraph 2.a. of Appendix A.

d. Corrects the chorine concentration unit in paragraph 4.a.(2) of Appendix A.

e. Corrects paragraph numbering in Appendix D.

f. Updates link in paragraph 3.b.(5). of Appendix D.

g. Corrects and clarifies information about bacteria testing in paragraph 4.b. of Appendix D

h. Corrects a paragraph reference in paragraph 1 Background of Appendix E.

As of February 16, 2021, this revised VHA directive:

a. Expands and clarifies the scope and applicability of the document.

b. Adds provisions on non-potable water.

c. Updates provisions on environmental *Legionella* testing and actions for potable water systems.

d. Updates definitions for *Legionella* disease surveillance.

3. RELATED ISSUES: VHA Directive 1131(5), Management of Infectious Diseases and Infection Prevention and Control Programs, dated September 17, 2017; VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated

January 29, 2016; VHA Engineering Standard-Cooling towers, VHA design manuals and specifications.

4. RESPONSIBLE OFFICE: The Assistant Under Secretary for Health for Support is responsible for the contents of this directive. Questions related to the application of this directive or engineering aspects may be directed to Healthcare Environment and Facilities Program, the Office of Healthcare Engineering (19HEFE) at OHE water safety@va.gov. Questions related to clinical aspects and validation processes in this directive may be directed to the National Infectious Diseases Service (11SPEC13) at 513-246-0270.

5. RESCISSIONS: VHA Directive 1061, Prevention of Healthcare-Associated *Legionella* Disease and Scald Injury from Potable Water Distribution Systems, dated August 13, 2014, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of February 2026. This directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Deborah E. Kramer
Acting Assistant Under Secretary for Health for Support

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: *Emailed to the VHA Publication Distribution List on February 17, 2021.*

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PREVENTION OF HEALTH CARE-ASSOCIATED *LEGIONELLA* DISEASE AND SCALD INJURY FROM WATER SYSTEMS

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for the prevention and control of health care-associated *Legionella* disease and possible related scald injury from water systems at Department of Veterans Affairs (VA) medical facilities. This directive addresses primary prevention for areas in health care with a recognized or potential higher risk for *Legionella* disease. Specifically, this directive pertains to the following areas at VA medical facilities:

a. VA-owned buildings in which patients, residents or visitors stay overnight such as, but not limited to, acute care facilities, Community Living Centers (CLCs), domiciliaries, Fisher Houses and temporary lodging facilities ("hoptels"). ***NOTE:*** *This includes VHA-owned buildings on the campus in which a tenant provides service that includes an overnight stay and VA maintains and operates the utilities for the building.*

b. VA-owned buildings where staff are required to sleep overnight as part of their job such as, but not limited to, fire stations.

c. Outdoor non-potable, aerosol-generating water systems such as, but not limited to, cooling towers and irrigation systems.

NOTE: *This directive focuses on primary prevention. Policy and guidance for full case investigations for confirmed or suspected health care-associated* Legionella *disease are not within the scope of this directive.* **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b).

2. BACKGROUND

a. *Legionella* is a Gram-negative bacterium that causes diseases collectively referred to as legionellosis. Legionellosis primarily consists of the respiratory diseases *Legionella* pneumonia (traditionally known as Legionnaires' disease and, hereafter, abbreviated as "LD" for "*Legionella* disease") and Pontiac Fever (a self-limiting influenza-like illness). Legionellosis is most often caused by the species, *Legionella pneumophila*; however, other species of *Legionella* can be pathogenic, particularly in transplant and other immunocompromised or high-risk patients. The bacteria, found naturally in water, have been associated with disease from potable and non-potable building water distribution systems. LD occurs after inhalation or aspiration of contaminated water, followed by a general incubation period of 2 to 14 days. LD can be severe, especially in hospitalized patients; however, legionellosis presents as a spectrum of illness and milder cases of pneumonia also may be caused by *Legionella*. *Legionella* are not considered transmissible from person-to-person, although there is one report in the literature of a probable person-to-person transmission.

b. Health care facilities are included in the types of buildings that have been associated with the transmission of *Legionella*. Cases of health care-associated LD (HCA LD) often arise from exposure to *Legionella* bacteria in hospital potable water distribution and process water systems.

c. In alignment with the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC) Legionellosis Case Report Form, VHA considers laboratory-confirmed cases to be "presumptive" HCA LD if a patient or resident of long-term care has spent equal to or greater than 10 continuous days in a health care facility in the 14 days prior to the onset of LD symptoms; or it is "possible" HCA LD, if a patient has spent a portion of the 14 days prior to LD symptom onset in a VA medical facility. ***NOTE:*** *In accordance with CSTE and CDC, the term "definite HCA LD" is no longer used and has been replaced with "presumptive HCA LD."*

d. This directive focuses on primary prevention activities for VA-owned buildings and water systems (see paragraph 1). However, determination of whether an LD case is presumptively or possibly associated with a VA medical facility must consider contact with all VHA health care settings, including hospitals, residential settings and clinics, whether VA-owned or leased. In the event of an LD case suspected to be associated with any VHA building, case investigation and consideration of secondary prevention activities to prevent further cases would be appropriate. ***NOTE:*** *Comprehensive policy for secondary prevention of LD cases is beyond the scope of this directive. For more information on case investigations of confirmed or suspected HCA LD, please see the following CDC link: https://www.cdc.gov/legionella/health-depts/healthcare-resources/cases-outbreaks.html.*

e. Persons at increased risk for LD include those with a compromised immune system (due to, for example, transplant, malignancy, renal disease or diabetes), those over 50 years of age, those with chronic lung disease and current or former smokers. However, LD cases reported in the medical literature indicate that the disease also may occur in seemingly healthy individuals.

f. Given the various factors and complexities associated with LD (e.g., host susceptibility, pathogen virulence, water distribution system configurations and water distribution system conditions), 100% prevention of LD is likely not possible. However, prevention and control practices can be implemented to reduce the risk of exposing people to *Legionella* in building and non-potable water systems. The HCA LD prevention activities in this directive involve assessing risks, monitoring water quality and implementation of commensurate engineering controls to limit the growth of *Legionella*. Use of engineering controls, such as water temperature and biocide levels, to limit *Legionella* growth includes ongoing monitoring of implemented controls, validating that the control measures are effective at inhibiting *Legionella* growth and modifying implementation or type(s) as necessary based on assessment of data. By focusing on engineering controls, this directive can be viewed as a horizontal intervention that can improve the overall microbiological quality of facility water in addition to inhibiting *Legionella* growth. ***NOTE:*** *For general information on water*

management programs for health care facilities and waterborne pathogens, please see the following CDC link: https://www.cdc.gov/hai/prevent/environment/water.html.

3. DEFINITIONS

NOTE: *The definitions in this section are provided in the context of* Legionella*,* Legionella *control or building and non-potable water management programs.*

a. **Anti-Scald Device.** Anti-scald device is a temperature actuated appurtenance used in plumbing systems to reduce/stop water flow exceeding a defined temperature. Individual anti-scald devices must meet the American Society of Sanitary Engineers (ASSE) 1062 Standard. Anti-scald devices may be add-on or integrated into plumbing fixtures or integrated into water tempering valves.

b. **Biocide.** A biocide is a chemical agent or substance that can deter, inactivate or kill microorganisms.

c. **Chlorination.** Chlorination is the application of sodium hypochlorite or other Environmental Protection Agency (EPA) approved form of chlorine, usually in the form of a solution, to the water distribution system.

d. **Chlorine.** Chlorine is an EPA listed biocide chemical (oxidant) approved for use in treatment of potable water to control/inactivate waterborne bacteria, viruses and protozoa. In high concentrations, used for disinfection of water systems and their components.

e. **Chlorine Dioxide.** Chlorine dioxide is an EPA listed biocide chemical (oxidant) approved for use in treatment of potable water to control/inactivate waterborne bacteria, viruses and protozoa.

f. **Clinical Testing.** Clinical testing encompasses the spectrum of diagnostic modalities that are used to elucidate the cause of a disease process. For diagnosis of LD, these clinical testing modalities include culture for *Legionella* species; *Legionella pneumophila* urinary antigen testing; serological testing for IgG and IgM antibodies from acute and convalescent sera; nucleic acid testing (e.g., *Legionella* polymerase chain reaction); and antibody/molecular diagnostic testing (such as direct fluorescent antibody testing, which is still available though it typically should not be used for diagnosis). It is expected that appropriate clinical testing will be conducted as standard practice by providers when caring for patients with a certain disease process.

g. **Clinical Validation.** Clinical validation is the process of determining if the primary engineering controls and any supplemental actions are successfully inhibiting *Legionella* growth in water distribution system(s) by monitoring the occurrence of HCA LD. For the purpose of this directive, clinical validation encompasses diagnostic testing of HCA pneumonia cases for LD when indicated and heightened awareness for diagnostic testing when *Legionella* is detected in environmental samples. ***NOTE:*** *See "Validation" in paragraph 3.ss*.

h. **Community-Associated *Legionella* Disease.** In general, community-associated *Legionella* disease (CA LD) is a laboratory-confirmed case of *Legionella* disease in which the patient has not had contact with the health care setting in the 14 days prior to onset of illness.

i. **Control Measure.** Control measure is any action or activity that can be used to prevent or eliminate a hazard or reduce the hazard to an acceptable level.

j. **Continual/Continuous Monitoring.** Continual/continuous monitoring refers to the almost uninterrupted monitoring and control of water quality, water pressure, biocide levels and water temperatures. This can be achieved through the use of automated measurement/control devices, typically connected to the Building Automation System (BAS), at various locations.

k. **Cooling Tower.** A cooling tower is a heat rejection device, which transfers waste heat to the atmosphere through the cooling of a water stream by using media to disperse the water, water spray systems and fans to enhance airflow. Cooling towers can be grouped into multiple cells however for the purpose of this document the term cooling tower means one fan and basin with associated fill and structure.

l. **Cooling Tower System.** A cooling-tower system consists of the equipment, piping and appurtenances associated with a cooling tower(s) used to transport the water to and from the cooling tower(s).

m. **Corrective Action.** A corrective action is any action to be taken to modify or correct the engineering controls when the results of monitoring indicate that a primary control measure(s) is not within the established control limits.

n. **Dead Leg.** A dead leg is a length of pipe with one end open to the system and the other end terminating at a cap, blind flange or closed valve.

o. **Disinfection.** Disinfection is an irreversible inactivation of microorganisms on a surface or in a system and reduction to non-hazardous levels. Disinfection for new installations or maintenance of piping, equipment and components is conducted in accordance with the requirements of the International Plumbing Code (IPC 2018), American Water Works Association (AWWA C651-05) and VA Master Construction Specifications.

p. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. ***NOTE:*** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

q. **Engineering Control Limit.** An engineering control limit is a minimum and maximum value at which a parameter must be maintained in order to prevent or eliminate a hazard or reduce the hazard to an acceptable level. For example, a minimum hot water temperature of 124 degrees Fahrenheit (°F) inhibits *Legionella* growth in building hot water systems.

r. **Environmental Validation.** See "Validation" in paragraph 3.ss. In this directive, environmental validation specifically refers to the process of testing water systems to determine if engineering controls are successfully inhibiting growth of *Legionella*.

s. **Flushing.** The flushing of outlets is the process of opening outlets such that hot and cold water flow out of the outlet for a specified amount of time to provide water with improved biocide, temperature and chemical composition to the piping system.

t. **Health Care-Associated *Legionella* Disease.** Health care-associated *Legionella* disease (HCA LD) is a laboratory-confirmed case of *Legionella* disease that is epidemiologically linked to the health care facility. HCA LD cases may be "presumptive" or "possible." The definitions in paragraphs 3.t.(1) and 3.t.(2) for these classifications are based on information in the CSTE Position Statement on case definitions for *Legionella* disease and the CDC Legionellosis Case Report form. ***NOTE:*** *Each case of LD must be assessed for linkage to the VA medical facility using the definitions in this paragraph on a case-by-case basis, and taking into account any related factors (e.g., a change in definition during a LD outbreak or molecular relatedness of patient and environmental isolates). Determination of association of a LD case with a VHA health care building is not limited to assessing exposure at only those buildings under the purview of this directive.*

(1) **Presumptive Health Care-Associated *Legionella* Disease.** Presumptive Health Care-Associated *Legionella* Disease (Presumptive HCA LD) is a laboratory-confirmed case of *Legionella* disease with contact at a health care facility continuously for 10 or more days within the 14 days prior to LD symptom onset. Overnight stays that can lead to this type of continuous contact within a VA medical facility include, but are not limited to, inpatient admissions, observation stays and CLC resident stays. ***NOTE:*** *In accordance with CSTE and CDC, the term "definite HCA LD" is no longer used and has been replaced with the term "presumptive HCA LD." As with the previous status category, "definite HCA LD," contact with a VA medical facility for "presumptive HCA LD" must be continuous for at least 10 days; however, the time period during which that contact may occur has been expanded to 14 days prior to the LD symptom onset.* In VHA, "presumptive HCA LD" is further categorized, below, based on when the contact with the VA medical facility occurred within that 14-day window:

(a) Presumptive Health Care-Associated *Legionella* Disease (Immediate) is a laboratory-confirmed case of *Legionella* disease in which the continuous 10-day or more exposure to the VA medical facility was immediately prior to the LD symptom onset date (i.e., the patient or resident did not leave the facility prior to the onset of symptoms). ***NOTE:*** *This corresponds to the former category known as "definite HCA LD."*

(b) Presumptive Health Care-Associated *Legionella* Disease (Not Immediate) is a laboratory-confirmed case of *Legionella* disease in which the continuous 10-day or more exposure to the VA medical facility was within the 14-day exposure window, but did not occur immediately prior to the LD symptom onset date (i.e., the patient or resident left the facility prior to the onset of symptoms).

(2) **Possible Health Care-Associated *Legionella* Disease.** "Possible Health Care-Associated *Legionella* Disease (Possible HCA LD)" is a laboratory-confirmed case of *Legionella* disease with contact at a health care facility for a portion of the 14 days prior to LD symptom onset (but less than 10 days of continuous exposure). In VHA, "possible HCA LD" is further categorized, below, based on the type of contact with the facility:

(a) Possible Health Care-Associated *Legionella* Disease (Inpatient) is a laboratory-confirmed case of *Legionella* disease in which a person had only inpatient or other overnight exposure to a health care facility for a portion of the 14 days prior to LD symptom onset (but less than 10 days of continuous exposure).

(b) Possible Health Care-Associated *Legionella* Disease (Outpatient/Non-Clinical) is a laboratory-confirmed case of *Legionella* disease in which a person had only non-overnight exposure to a health care facility in the 14 days prior to onset of illness. Non-overnight exposure includes, for example, outpatient clinic visits or non-clinical activities, such as picking up a pharmacy prescription or attending bingo at the health care facility.

(c) Possible Health Care-Associated *Legionella* Disease (both Inpatient and Outpatient/Non-Clinical) is a laboratory-confirmed case of *Legionella* disease in which the person had both inpatient and outpatient/non-clinical exposure to a health care facility for a portion of the 14 days prior to LD symptom onset (but less than 10 days of continuous exposure).

u. **Health Care-Associated *Legionella* Disease Prevention Plan.** The health care-associated *Legionella* disease (HCA LD) prevention plan is the written plan required for every building or outdoor device under the purview of this directive at a VA medical facility. The HCA LD prevention plan focuses on identification of risks and implementation of engineering measures for control of *Legionella* growth, monitoring of the control measures, validation that the measures are effective at suppressing *Legionella* growth and implementation of corrective actions when indicated.

v. **Hyper-Chlorination.** Hyper-chlorination is a remediation process that involves the addition of sodium hypochlorite to a water distribution system above routine levels for a specified duration for remediation purposes.

w. **Immersion Bath.** An immersion bath is a bath in which an individual's entire body, or a body part, is submerged in water.

x. ***Legionella.*** *Legionella* is the genus name of a group of Gram-negative bacteria that are naturally found in water and have been associated with building water

distribution systems and cooling towers. Over 50 species and 70 serogroups have been identified.

y. ***Legionella* Disease.** *Legionella* disease (LD) is the term used in this directive for the disease traditionally known as "Legionnaires' disease;" a type of pneumonia caused by pathogenic species of the bacterium, *Legionella*. Most, but not all, cases of LD in the United States are caused by the species, *Legionella pneumophila* serogroup 1.

z. **Legionellosis.** Legionellosis refers to diseases (Legionnaires' disease, Pontiac Fever, extrapulmonary legionellosis) caused by pathogenic species of the bacterial genus, *Legionella*. Legionnaires' disease is defined above (see "*Legionella* disease"). Pontiac fever is a milder respiratory infection with no indication of pneumonia; symptoms resolve without treatment. Extrapulmonary legionellosis is infection with *Legionella* at a site other than the lungs; occurrence is rare and often in immunocompromised patients.

aa. **Legionnaires' Disease.** See "*Legionella* disease".

bb. **Low Flow Fixtures.** Low flow fixtures are fixtures that either due to modification or age have flow capabilities below the standard IPC requirements. Low flow fixtures are similar to irregularly used fixtures, which are fixtures that are used less than once a day.

cc. **Mitigation.** Mitigation is a process of undertaking an action or set of actions to reduce the severity of a situation.

dd. **Mixing Valve.** Mixing valve is a generic reference to a class of water tempering devices. Mixing valves used for tempering hot water in potable water systems must meet the requirements of the International Plumbing Code (IPC 2009), American Society of Sanitary Engineers (ASSE 1016/1069/1070) and VA Master Construction Specifications.

ee. **Monitoring.** Monitoring, for the purpose of this directive, refers to the process of measuring water quality of incoming water (from municipal or central plant) and at representative outlets/areas to determine if the engineering controls are within established minimum and maximum limits.

ff. **Monochloramine.** Monochloramine is a type of chloramine. Chloramines are most often formed when ammonia is added to chlorine. Monochloramine is an EPA listed biocide chemical (oxidant) approved for use in treatment of potable water to control/inactivate waterborne bacteria, viruses and protozoa.

gg. **Non-Potable Water System.** A non-potable water system is a water system primarily used for non-drinking purposes such as aesthetic use or industrial use (e.g., cooling towers and irrigation systems).

hh. **Outlet.** An outlet is a point in the potable water distribution system where an individual (also known as the "end user") accesses the water. Examples include faucets, showers, ice machines and drinking fountains.

ii. **Oxidant Residual.** An oxidant residual is an indication of the amount of available oxidant present in the water system and at the outlet after system demand has been satisfied.

jj. **Point-of-Use Filter.** Point-of-use filter refers to a micropore (approximately 0.2 micrometer) filter specifically designed for use in preventing the passage of bacteria, such as *Legionella*, present in water. Typically, these filters are fitted to water outlets or installed in water supply lines proximal to equipment (e.g., ice machines, drinking fountains).

kk. **Potable Water System.** A potable water system is a water distribution system (for both hot water and cold [unheated] water) within a building or structure that is primarily used for drinking, sanitation, food service or personal hygiene, which meets EPA and state drinking water standards.

ll. **Potable Water Treatment.** Potable water treatment is a permanently installed system that is designed and installed to inject a biocide into the potable water system to provide additional treatment to the water supplied by the municipality or utility. The system(s) normally operate continuously to maintain biocide levels in the building and must be permitted by the state for operation.

mm. **Primary Control Measures.** Primary control measures are the main or routine methods used to suppress *Legionella* growth in building potable water distribution systems. The primary control measures often used in building potable water distribution systems include at least one of the following: appropriate water temperature(s) and biocide(s) levels (e.g., oxidizing agent).

nn. **Remediation.** Remediation is the process of implementing actions to reduce the amount of *Legionella* in a water distribution system through actions such as the addition of a biocide or increasing the temperature to inactivate bacteria through thermal means.

oo. **Resident.** Resident is defined here for the purpose of clarifying which buildings fall subject to this directive. In the phrase, "VHA buildings in which patients, residents or visitors stay overnight", the term "resident" refers to Veterans who are under residential-type care such as provided at a Community Living Center or domiciliary.

pp. **Schematic Diagram.** A schematic diagram is a single line schematic representation of the entire building water distribution system (including process equipment, controls and general system layout) to facilitate a full understanding of the system interconnection and operational parameters. This diagram includes all major equipment and its relation to the system, including water heaters, tanks, pumps and instrumentation. ***NOTE:*** *This is not to be confused with a process flow diagram, which is a simple diagram of the system.*

qq. **Supplemental Action.** A supplemental action is a process, system or action executed in addition to the routine (primary) control measures (such as temperature and biocide control) to facilitate the inhibition of *Legionella* growth in building water distribution systems.

rr. **Thermal Remediation.** Thermal remediation is the temporary resetting of the temperature in the water distribution system to 160°F - 170°F (71°C - 77°C) while continuously flushing each outlet in the system for at least 30 minutes (also known as “super heat and flush" and “thermal eradication”) to remediate the system.

ss. **Validation.** Validation is the process of obtaining evidence that a plan is effective. In this directive, validation specifically refers to verifying that control measures, and any supplemental actions, are effective at inhibiting the growth of *Legionella* in building potable water distribution systems or non-potable systems. The two validation methods used are environmental water testing for *Legionella,* and clinical testing of pneumonia patients for *Legionella*.

tt. **VHA Building.** VHA buildings are individual buildings associated with a VA medical facility. The term is used in this directive because only certain VHA-owned buildings at a VA medical facility are required to have an HCA LD prevention plan.

uu. **Water Distribution System.** Water distribution system is a system used for the distribution of water (site and building) which includes all piping, water treatment, equipment, controls, fixtures and components.

vv. **Water System Management Point.** A specific location, device, fixture, or water distribution system component used for the monitoring of conditions or performance or the control of the system or its individual components.

4. POLICY

a. It is VHA policy that ongoing HCA LD prevention, including provisions necessary for the prevention of scald injury, will be implemented in all VA medical facilities for:

(1) VHA-owned buildings in which patients, residents or visitors stay overnight;

(2) VHA-owned buildings in which staff are required to sleep overnight; and

(3) Outdoor non-potable, aerosol-generating water systems such as cooling towers.

b. This program must be established with written policy in accordance with, at a minimum, the requirements outlined in this directive.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring that sufficient resources and funding are available to attain both Veteran Integrated Service Network (VISN) and VA medical facility compliance with this directive.

(2) Ensuring overall VHA compliance with directive.

b. **Assistant Under Secretary for Health for Support.** The Assistant Under Secretary for Health for Support is responsible for establishing policy and providing guidance and oversight as necessary to ensure the timely and successful implementation of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards and applicable regulations.

d. **Director of the Healthcare Environment and Facilities Program, Office of Healthcare Engineering.** The Director of the Healthcare Environment and Facilities Program (HEFP), Office of Healthcare Engineering (OHE), is responsible for:

(1) Overseeing VHA's program for prevention of HCA LD and scald injury from water systems.

(2) Periodically assessing VHA's program for the prevention of health care-related LD and scald injury from water systems for continued need, currency and effectiveness.

(3) Developing and issuing any additional engineering requirements, standards and guidelines for the prevention of LD. ***NOTE:*** *HEFP regularly updates these supportive documents as needed and they can be found at the VHA Water Safety Management & Legionella Resources website at http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella.This is an internal VA websites that are not available to the public.*

(4) Conducting assessments and surveys related to the implementation and ongoing monitoring of this directive as related to engineering requirements.

(5) Providing consultative assistance related to engineering requirements to VISNs and VA medical facilities, as needed.

(6) Administering the Water Safety Management Tool (located at the VHA Water Safety Management & Resources website), or most current reporting system, for the

collection of environmental data to facilitate analysis and action. Actions are defined in the appendices of this directive and will be dependent on findings.

e. **Director of the National Infectious Diseases Service.** The Director of the National Infectious Diseases Service (NIDS) is responsible for:

(1) Developing procedures and guidelines within VHA for *Legionella* prevention in conjunction with other VHA program offices, as necessary. ***NOTE:*** *Supportive documents and guidelines can be found at the Water Safety Management &* Legionella *Resources site at http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA website that is not available to the public.*

(2) Managing the centralized collection of LD case data from VA medical facilities through the following:

(a) Reviewing LD case data (presumptive HCA LD, possible HCA LD and community-associated LD) reported by VA medical facilities (see paragraph 5.g.(8)(b)) at least annually to understand LD rates and trends in VHA.

(b) Contacting the VISN and VA medical facility for additional information regarding LD cases, as necessary.

(c) Providing consultative assistance to VISNs and VA medical facilities related to LD risk, clinical aspects of LD and validation requirements, as needed.

f. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and any policies and guidance from VHA Central Office for prevention of HCA LD, prevention of scald injuries and water safety.

(2) Prioritizing resources and funding for implementation of this directive for all VA medical facilities within the VISN.

(3) Ensuring completion of annual HCA LD prevention plans, reporting requirements and clinical and environmental testing by all VA medical facilities within the VISN.

(4) Assigning a VISN-level staff member that reports to VISN leadership as the VISN Water Safety Liaison for communication between VHA Central Office and VISN or VA medical facility staff regarding water safety and *Legionella* prevention actions, policies and guidance.

(5) Working with VA medical facility Directors to identify a representative within the VISN to participate on the Facility Water Safety Committee when the VA medical facility does not have a required member (e.g., Infectious Diseases). See paragraph 5.g.(1).

(6) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

g. **Veterans Integrated Services Network Water Safety Liaison.** The VISN Water Safety Liaison is responsible for:

(1) Obtaining and reviewing annual HCA LD prevention plans, reports and clinical and environmental testing from all VA medical facilities within the VISN. This includes the collection and analysis of data indicating VA medical facility compliance with this directive and reporting requirements as well as analysis and validation of WSMT data and consultation with VA medical facilities to improve performance.

(2) Coordinating communication between VHA Central Office and VISN or VA medical facility staff regarding water safety and *Legionella* prevention actions, policies, guidance or events, as needed.

(3) Being knowledgeable of VHA policies and guidance for prevention of HCA LD, prevention of scald injuries and water safety.

(4) Developing VISN-level policy and procedure related to HCA LD prevention.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that the VA medical facility maintains a multi-disciplinary Facility Water Safety Committee that is chaired by the VA medical facility Associate Facility Director, or equivalent, and reports to the VA medical facility Director. This committee must include, at minimum, representation from the following areas: Engineering/Facilities Management, Infectious Diseases, Infection Prevention and Control, Pathology and Laboratory Medicine, Hemodialysis (if performed on site), Safety/Industrial Hygiene, Occupational Health and Environmental Management Service. ***NOTE:*** *If the VA medical facility does not have a required member (e.g., Infectious Diseases) then the VA medical facility Director must work with the VISN Director to identify a representative within the VISN to participate on the Facility Water Safety Committee. Other stakeholders in VA medical facility water use (e.g., labor partners, dental, sterile processing and supply) may be included on the Facility Water Safety Committee, as appropriate.*

(2) Establishing a VA medical facility HCA LD prevention policy, which specifies responsibilities and incorporates the requirement for written HCA LD prevention plans in alignment with the appendices of this directive.

(a) This VA medical facility policy must include a listing of all buildings and outdoor non-potable water systems and equipment that require an HCA LD prevention plan as defined in this directive.

(b) The policy must be reviewed and updated at least every 5 years or when a change in use of areas is implemented, major renovations are executed or new space is constructed.

(3) Ensuring that each building and outdoor non-potable, aerosol-generating water system subject to this directive has a written HCA LD prevention plan and approving these plans. (See Appendix A.)

(a) Requirements for building HCA LD prevention plans are detailed in Appendix A, with provisions necessary for the prevention of scald injury in Appendix B and validation requirements in Appendix C. Requirements for HCA LD prevention plans pertaining to cooling towers are listed in Appendix D with requirements for other outdoor water devices in Appendix E. The written HCA LD prevention plans also must consider any supportive guidance issued by VHA. ***NOTE:*** *Supportive documents and guidelines can be found at the Water Safety Management &* Legionella *Resources site at http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA websites that are not available to the public.*

(b) Multiple buildings and outdoor non-potable water systems may have HCA LD prevention plans collated into one document if each building/non-potable system is described in its own section that identifies unique features and plans associated with each item.

(c) The written HCA LD prevention plan(s) must be reviewed, updated as necessary and recertified through the VISN at least annually. This recertification must be communicated to the VISN Water Safety Liaison.

(4) Ensuring that the actions in the written HCA LD prevention plan(s) are implemented.

(5) Ensuring that the VA medical facility has decommissioned all indoor and outdoor, open, decorative water features, and that future design plans do not include the installation of indoor and outdoor, open, decorative water features. ***NOTE:*** *This requirement does not apply to open water features installed for a non-decorative purpose such as devices used to aerate ponds (refer to Appendix E for additional information).*

(6) Ensuring that environmental water testing for *Legionella* is conducted for designated potable (see Appendix C, paragraph 2.a.) and non-potable (see Appendix D, paragraph 4.a.) water in accordance with this directive and its appendices, and that results are submitted to the VHA Water Safety Management Tool, or most current reporting system, as specified in the reporting system User Manual.

(7) Providing an annual summary of the VA medical facility's clinical *Legionella* testing results and number of cases of LD (presumptive HCA LD, possible HCA LD and community-associated LD) to the VISN Director.

(8) Ensuring that cases of LD (VA-associated and community-associated) are:

(a) Reported to the appropriate public health authority in accordance with applicable statutes and regulations as well as the current VHA directive regarding infectious disease reporting, and protection and disclosure of health information (see VHA

Directive 1131(5), Management of Infectious Diseases and Infection Prevention and Control Systems, dated November 7, 2017).

(b) Reported to both the VHA Inpatient Evaluation Center (IPEC) *Legionella* Case Report data module and the IPEC *Legionella* Clinical Information data module, or most current reporting system, as specified in the reporting system User Manual. ***NOTE:*** *The User Manual for the* Legionella *reporting modules in IPEC can be found at the Water Safety Management &* Legionella *Resources site at http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA website that is not available to the public.*

(9) Requesting consultative assistance from HEFP OHE, NIDS or the VISN Water Safety Liaison on issues related to *Legionella* prevention efforts, if needed.

i. **VA Medical Facility Chief of Staff and VA Medical Facility Associate Director of Patient Care Services.** The VA medical facility Chief of Staff and the VA Medical Facility Associate Director of Patient Care Services are responsible for:

(1) Collaborating to ensure that the VA medical facility has access to clinical care staff with expertise in *Legionella* pneumonia to assist in diagnosis and treatment (e.g., infectious diseases, pulmonology, general internal medicine). ***NOTE:*** *Diagnostic testing of pneumonia patients for LD, especially when health care-association is suspected, can provide important information for surveillance and remediation purposes. Full details on requirements and recommendations for clinical testing and diagnostic awareness can be found in Appendix C.*

(2) Collaborating to ensure that clinical staff involved in direct patient care are notified in a timely manner when cases of presumptive or possible HCA LD are identified to increase diagnostic awareness (see Appendix C, paragraph 4).

(3) Collaborating to ensure that clinical staff involved in direct patient care are notified in a timely manner when routine environmental water testing is positive for *Legionella,* to increase diagnostic awareness (see Appendix C, paragraph 3 for more information).

j. **VA Medical Facility Chief Engineer or VA Medical Facility Manager.** ***NOTE:*** *VA medical facility Chief Engineer and VA medical facility Manager are used interchangeably to indicate engineering leadership.* The VA medical facility Chief Engineer or VA medical facility Manager or equivalent is responsible for:

(1) Documenting the VA medical facility's policy and engineering procedures for the implementation and monitoring of temperature and biocide limits in the hot and cold potable water distribution systems (e.g., hot water tanks, if used, circulating water in the distribution systems and at the outlets) in accordance with Appendices A and B and the VA medical facility's approved HCA LD prevention plan(s).

(2) Ensuring maintenance of appropriate water temperatures and biocide levels in the hot and cold potable water distribution system(s) in accordance with Appendices A and B, the VA medical facility's approved policy and HCA LD prevention plan(s).

(3) Ongoing monitoring, data analysis, corrections to engineering controls (if required) and documentation of the temperature and biocide levels in the water distribution system(s) as well as corrective actions implemented to ensure they are within the requirements defined in Appendices A and B and the VA medical facility's approved HCA LD prevention plan(s).

(4) Continuous monitoring of incoming water quality (from municipal or central plant sources) as required in Appendix A and the VA medical facility's approved HCA LD prevention plan(s).

(5) Ensuring that when a potable water treatment system that injects biocide into the system is present on a building potable water system, an operating permit is in place. The appropriate biocide levels for *Legionella* control in the building's potable water distribution system(s) must be maintained in accordance with the permit and Appendix A, and in compliance with applicable EPA and local requirements for safe drinking water and effluent concentrations.

(a) Biocide-based water treatment systems must comply with applicable law and regulations, which typically identify acceptable biocide(s) and specify construction and operating requirements. Installed systems must be specifically approved or recognized for the intended use by the State regulatory water authority. Documentation of system(s) approval, design, installation and operation must be maintained and current.

(b) Documentation of the VA medical facility's policy for biocide concentration levels in the hot and cold potable water distribution systems. This includes documentation of minimum and maximum biocide levels, allowable disinfection byproduct levels, biocide monitoring method and frequency and any other requirements in accordance with Appendix A and in compliance with operating permits.

(c) Ongoing monitoring of biocide and disinfection byproduct levels in the building's potable water distribution systems to ensure they are within the guidelines defined in Appendix A and in compliance with operating permit requirements.

(d) Ensuring that any potable water treatment system implemented in a building potable water distribution system is functioning according to the manufacturer's specifications for the treatment system that is being used and at recommended capacity for *Legionella* inhibition.

(6) Documenting the VA medical facility policy for cooling towers in accordance with Appendix D and other outdoor non-potable, aerosol-generating water systems in accordance with Appendix E. The policy must provide an overview of the equipment and systems on site, define who is responsible for the equipment and systems and establish the general operational and testing requirements to ensure the systems operate as designed and the potential for aerosolizing pathogens is mitigated.

(a) Ensuring there is a written Cooling Tower Management Plan as part of the HCA LD prevention plan(s) and that there is documentation of engineering procedures and actions according to the requirements in Appendix D.

(b) Ensuring implementation of requirements for the maintenance, cleaning and monitoring of cooling towers (refer to Appendix D) and other outdoor aerosol-generating water systems (refer to Appendix E) at the VA medical facility.

(c) Documentation of the VA medical facility's policy for biocide concentration levels in the cooling tower and distribution systems. This includes documentation of minimum and maximum biocide levels, biocide monitoring method and frequency and any other requirements in accordance with Appendix D.

(d) Ongoing monitoring and documentation of biocide and chemistry in the cooling tower and cooling tower systems to ensure they are within the guidelines defined in Appendix D and the VA medical facility's approved Cooling Tower Management Plan(s).

(7) Ensuring an Infection Control Risk Assessment is conducted in cooperation with other VA medical facility stakeholders, to address the potential impact of construction and maintenance of water systems on growth or transmission of waterborne pathogens and to determine the extent of precautions, disinfection and system or component commissioning requirements.

(8) Ensuring that newly installed potable water piping, equipment and distribution system components are flushed of debris and disinfected prior to being placed into service as defined by VHA specifications (https://www.cfm.va.gov/til/) and American Water Works Association (AWWA) through the following:

(a) Documentation of flushing and disinfection must be maintained for at least 3 years.

(b) Equipment must be commissioned to ensure operation meets the design intent (i.e., water heaters, circulation pumps, injections systems) and documentation retained for 3 years for record.

(c) Newly installed water piping, equipment and distribution system components that had been disinfected but not put into use within a week of the action must be disinfected again prior to building occupancy due to stagnation of water in the system.

(9) Ensuring the VA medical facility has a plan for removal of unused potable water branch lines and dead legs and capping at the main supply/recirculation supply lines to limit stagnation and the potential for *Legionella* growth.

(10) Ensuring that only steam is used for building humidification purposes. See VA HVAC Design Manual at https://www.cfm.va.gov/til/dManual.asp. The use of ultrasonic humidifiers, foggers, misters, spray humidifiers or tank type humidifiers is prohibited.

(11) Assessing and documenting competency of contractors and the contractor's personnel as part of the acquisition process prior to the start of any work on VA medical facility water systems, including water treatment. Competencies must be re-assessed on an on-going basis, or whenever there is a change in contractors or the contractor's personnel performing the work. At a minimum, the contractor's competency must be assessed and documented on an annual basis. A copy of any assessment or documentation must be submitted to the contracting officer and retained in the VA medical facility file.

(12) Ensuring competent VHA personnel are available to address water system operations issues within a reasonable response time as defined by the site-specific risk assessment and site policy.

(13) Coordinating notification to all VA medical facility employees when:

(a) Maintenance and repair procedures will be taking place that could affect the water system;

(b) Maintenance and repair procedures have been completed; and

(c) Affected systems have been tested and are returned to normal operation.

(14) Providing the Facility Water Safety Committee; Facility Safety and Health Leadership Committee; and Infection Prevention and Control Committee with an annual report of the water system maintenance and monitoring, in addition to any *Legionella* mitigation actions taken (see VHA Directive 7701, Comprehensive Occupational Safety and Health Program, dated May 5, 2017 and VHA Directive 1131(5), Management of Infectious Diseases and Infection Prevention and Control Systems, dated November 7, 2017).

k. **VA Medical Facility Chief of Pathology and Laboratory Medicine.** The VA medical facility Chief of Pathology and Laboratory Medicine Service is responsible for:

(1) Ensuring that the laboratory has access to *L. pneumophila* urinary antigen testing. VHA-designated Transplant Centers need to consider on-site availability of *L. pneumophila* urinary antigen testing. ***NOTE:*** *Considerations must be made to ensure the turnaround time for* L. pneumophila *urinary antigen testing results is in a clinically relevant time frame--ideally within 24 hours and no more than 96 hours.*

(2) Ensuring access to a clinical laboratory that can perform cultures on respiratory secretions for *Legionella*, with identification at the species level, and can determine the serogroup of *L. pneumophila.*

(3) Ensuring that clinical tests for detection of *Legionella* infection are performed in accordance with current VHA policy on laboratory testing (see VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated July 27, 2018; VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated January 29, 2016).

(4) Ensuring that results from laboratory tests and clinical cultures for *Legionella* are entered into the electronic health record (EHR) as soon as testing is completed.

(5) Providing the Infection Prevention and Control Committee and the Facility Water Safety Committee the following annual data:

(a) Total number of diagnostic tests (e.g., urinary antigen, clinical cultures, serology, direct fluorescent antibody/immunohistochemistry and nucleic acid assay) for *Legionella* ordered; and

(b) Total number of persons with positive results for *Legionella.*

l. **VA Medical Facility Infection Prevention and Control Personnel.** The VA medical facility Infection Prevention and Control Personnel are responsible for ensuring participation of the VA medical facility infection prevention and control program in at least the following activities related to *Legionella* prevention:

(1) Facility Water Safety Committee activities, especially as they pertain to assessment of risk for HCA LD.

(2) Validation that HCA pneumonia patients are being tested for LD, especially if the VA medical facility is in a heightened state of awareness for *Legionella* diagnostic testing (see Appendix C, paragraph 3).

(3) Facilitation of the development of Infection Control Risk Assessments for construction and maintenance activities.

m. **VA Medical Facility Water Safety Committee Chair.** The VA medical Facility Water Safety Committee Chair is responsible for:

(1) Conducting an annual assessment to determine which buildings and outdoor non-potable, aerosol-generating water systems are subject to this directive. These buildings and systems must be listed in the medical facility policy on HCA LD prevention.

(2) Developing written HCA LD prevention plan(s) for the following locations:

(a) Each building subject to this directive (see paragraph 1), in accordance with this directive's requirements and in consideration of any supporting guidance issued by VHA. The written HCA LD prevention plan(s) must contain, at minimum, all the components identified in Appendix A, paragraph 1. These components address building associated risk assessments (see Appendix A), implementation and monitoring of engineering controls (see Appendices A and B) and validation that the engineering controls are effectively preventing *Legionella* growth (see Appendix C) and scald injuries (see Appendix B).

(b) Each cooling tower and other outdoor non-potable water-related devices at the VA medical facility, in accordance with this directive's requirements and in consideration

of any complimentary guidance, VHA directive or standard issued by VHA HEFP. If the cooling tower is associated with a building subject to this directive, then the Cooling Tower Management Plan can be incorporated into the building's HCA LD prevention plan as a specific section. Cooling tower requirements can be found in Appendix D. Requirements for other outdoor water systems subject to this directive can be found in Appendix E. ***NOTE:*** *The requirements for cooling towers and non-potable water systems subject to this directive include having a risk assessment conducted and documented at least annually as part of the HCA LD prevention plans.*

(3) Reviewing the written HCA LD prevention plan(s) at least annually for accuracy and updating, as necessary.

(4) For each building and cooling tower system subject to this directive, establishing the plan for conducting environmental water testing for *Legionella*, to include the following:

(a) Determining the number and location of water samples to be tested and the frequency of such testing. This must be in accordance with the testing requirements for buildings in Appendix C, paragraph 2.a. and for cooling towers in Appendix D, at a minimum. ***NOTE:*** *Testing water from other non-potable systems that are subject to this directive (Appendix E) is not required unless the VA medical facility risk assessment of these systems identifies the need.*

(b) Determining who at the building level is responsible for the following: collecting environmental water samples, ensuring that the water samples are transferred to the environmental testing laboratory, receiving the results and then reporting the results to the Facility Water Safety Committee, the Facility Safety and Health Leadership Committee and the Infection Control Committee.

(c) Determining the laboratory that will conduct the environmental water testing using the requirements in Appendix C, paragraph 2.b.

(5) Conducting routine committee meetings at least quarterly. The meetings must include, at a minimum, review of building associated risk(s); documented verification of policy implementation (e.g., implementation of engineering controls, water quality testing, water pressure, scald control); any results from water testing for *Legionella* and how recent test results compare to previous results; whether any engineering controls were not within specified limits and why that may have occurred; whether any corrective actions were taken on engineering controls; whether the HCA LD prevention plan(s) need to be updated; and whether there have been any cases of LD diagnosed at or potentially associated with each building. These discussions can be facilitated by visual representation (e.g., graphing) of validation data (see Appendix C). ***NOTE:*** *If the Facility Water Safety Committee discusses any case of LD, patient information must be de-identified prior to sharing the information with the committee.*

(6) Meeting as necessary to address any non-routine *Legionella* control issues and HCA LD.

(7) Documenting in the minutes any corrective actions that were initiated for maintaining water temperature and oxidant residuals at appropriate levels to inhibit *Legionella* growth and documenting the effectiveness of these corrective actions.

(8) Ensuring the results of such reviews are communicated to the VA medical facility Leadership team, Facility Safety and Health Leadership Committee, Infection Prevention and Control Committee and any other local committees as appropriate for the respective VA medical facility.

n. **Manager, VA Medical Facility Occupational Safety and Health Service.** The VA medical facility Manager, Occupational Safety and Health Service, is responsible for anticipating and evaluating exposures and recommending controls for occupational safety and health exposures, as they relate to water system maintenance, monitoring and remediation in this directive, in accordance with VHA Directive 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016, or most current VHA policy.

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

8. REFERENCES

a. 38 U.S.C. § 7301(b).

b. 40 C.F.R. Part 141.

c. 40 C.F.R. Part 142.

d. VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated July 27, 2018.

e. VHA Directive 1131(5), Management of Infectious Diseases and Infection Prevention and Control Programs, dated September 17, 2017.

f. VHA Directive 7701, Comprehensive Occupational Safety and Health Program, dated May 5, 2017.

g. VHA Directive 7702, Industrial Hygiene Exposure Assessment Program, dated April 29, 2016.

h. VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated January 29, 2016.

i. American Society for Heating, Refrigerating and Air-conditioning Engineers (ASHRAE). Guideline 12-2020. Minimizing the Risk of Legionellosis Associated with Building Water Systems; 2020

j. American Society for Heating, Refrigerating and Air-conditioning Engineers (ASHRAE). Standard 188-2018. Legionellosis: Risk Management for Building Water Systems; 2018.

k. American Thoracic Society and Infectious Diseases Society of America. Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated and Healthcare-associated Pneumonia. American Journal of Respiratory and Critical Care Medicine. 171(4):388-416; 2005.

l. Centers for Disease Control and Prevention. Guidelines for Environmental Infection Control in Health-care Facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Morbidity and Mortality Weekly Reports. 52 (RR10):1-42; 2003. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm.

m. Centers for Disease Control and Prevention. Guidelines for Preventing Healthcare-associated Pneumonia. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. Morbidity and Mortality Weekly Reports. 53(RR03):1-36; 2004. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm.

n. Centers for Disease Control and Prevention. Website: *Legionella* (Legionnaires' Disease and Pontiac Fever). https://www.cdc.gov/legionella/.

o. Centers for Disease Control and Prevention. Legionellosis Case Report form. https://www.cdc.gov/legionella/downloads/case-report-form.pdf. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

p. Centers for Disease Control and Prevention. Toolkit: Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings: A Practical Guide to Implementing Industry Standards. June 5, 2017.

q. Centers for Medicare & Medicaid Services. Requirement to reduce *Legionella* risk in health care facility water systems to prevent cases and outbreaks of Legionnaires' disease (LD). https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-30.pdf.

r. Council of State and Territorial Epidemiologists. Revision to the Case Definition for National Legionellosis Surveillance. Position Statement 19-ID-04. https://cdn.ymaws.com/www.cste.org/resource/resmgr/2019ps/final/19-ID-

04_Legionellosis_final.pdf. ***NOTE:*** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

s. Cooling Tower Institute Standards. Methods for Cooling Water System Microbial Monitoring (WTG-130C): Application of Oxidizing biocides (WTP-141), Legionellosis (WTP 148).

t. Department of Veterans Affairs HVAC and Plumbing Design manuals https://www.cfm.va.gov/til/dManual.asp.

u. Environmental Protection Agency. Technologies for *Legionella* Control in Premise Plumbing Systems: Scientific Literature Review. Office of Water, EPA 810-R-16-001. Published September 2016. https://www.epa.gov/sites/production/files/2016-09/documents/legionella_document_master_september_2016_final.pdf.

v. International Code Council. International Plumbing Code, Chapters 1-6 2009 IPC. International Code Council, Inc.; 2009.

w. Kalil AC, Metersky ML, Klompas M, Muscedere J, Sweeney DA, et al., Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clinical Infectious Diseases* 63(5): e61-e111; 2016.

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y. New York State Department of Health. "Part 4 – Protection against *Legionella*: Appendix 4-A – Interpretation of *Legionella* Culture Results from Cooling Towers". July 6, 2016. https://regs.health.ny.gov/volume-title-10/1339572150/appendix-4-interpretation-legionella-culture-results-cooling-towers.

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HEALTH CARE-ASSOCIATED *LEGIONELLA* DISEASE PREVENTION PLANS FOR BUILDING POTABLE WATER SYSTEMS

1. COMPONENTS OF A POTABLE WATER HEALTH CARE-ASSOCIATED *LEGIONELLA* DISEASE PREVENTION PLAN

A health care-associated (HCA) *Legionella* disease (LD) prevention plan for each building under the purview of this directive (see paragraph 1) must include:

a. Schematic (single line) diagrams of the potable water systems for the medical campus and each building (hot and cold water) under the purview of this directive. Each diagram must be kept current and include equipment, instrumentation, monitoring equipment and depiction of how water is distributed, circulated, stored, heated and cooled, treated and monitored. The diagrams must be accurate representations of existing conditions and identify any areas in which water is processed differently (e.g., hemodialysis). All equipment must be uniquely identified with an equipment number and cross-referenced with an equipment list in the plan that defines the salient characteristics of the equipment.

b. A risk assessment of each building subject to the directive for HCA LD. At least annually, assess the building for factors that may indicate increased risk for HCA LD. Factors include, but are not limited to: patient population risk factors; presence of building functions associated with increased risk (e.g., transplant units); presence of devices with increased risk of inhalation or aspiration of water (e.g., whirlpool tubs, ice machines); past cases of presumptive or possible HCA LD (or past cases of definite HCA LD, using previous epidemiologic case definitions); ability to implement engineering controls to prevent *Legionella* growth; past positive environmental testing results (in the specific building or elsewhere at the Department of Veterans Affairs (VA) medical facility); and location of the building in an area of the country with recognized higher incidence of LD. Evaluation of previous years' HCA LD plans and their findings also must be included in the current risk assessment. ***NOTE:*** *Additional information on building risk assessments can be found at the Veterans Health Administration (VHA) Water Safety Management and Legionella Resources intranet site located at: http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA website that is not available to the public.*

c. Identification of water system management points for the building's potable water distribution system(s), as shown on the schematic diagrams, where monitoring and controls are implemented to prevent the growth of *Legionella* and prevent scald injury.

d. Establishment of engineering control strategies. Specifically:

(1) Establish the engineering control limits for the system to inhibit *Legionella* in the environment (see paragraph 2 below).

(2) Identify engineering control equipment and methods used for preventing scald injury from water that is too hot (see Appendix B).

(3) Establish a schedule to routinely monitor implementation of the engineering control strategies in the building water systems. ***NOTE:*** *Since this directive focuses on the implementation of engineering controls to prevent* Legionella *growth, "monitoring" refers to assessment of the engineering control measures (e.g., water temperature, biocide level) defined in the HCA LD prevention plan, not the amount of* Legionella*. Rather, assessment of* Legionella *in the water distribution must be included as a mechanism to validate that the engineering controls are effective.*

(4) Establish a dead leg control, elimination and prevention plan. Plan components include: identification of existing dead legs; dead leg risk assessment; removal prioritization; removal schedule; and process to prevent the installation or modification of systems that will result in a dead leg.

e. Defining and documenting when each water quality and control measure is monitored for condition compliance and corrective action taken (what and when).

f. Validation that the control measures are effectively inhibiting *Legionella* growth (see Appendix C).

2. ENGINEERING CONTROL STRATEGIES AND LIMITS FOR ONGOING PREVENTION OF *LEGIONELLA* GROWTH

Maintenance of appropriate water temperatures and biocide levels (as necessary) comprise the primary control measures used to inhibit *Legionella* growth in the potable water distribution systems of buildings under the purview of this directive. The building's potable water distribution system(s) must be maintained and monitored in accordance with the following requirements:

a. **Water Quality and Pressure Monitoring.** Potable water entering each building subject to this directive must be continuously monitored for incoming water pressure and the following characteristics: temperature, pH, and biocide levels. Data must be reviewed on a routine basis (a minimum of weekly) for indication of action levels and changes that may affect *Legionella* control in the building. ***NOTE:*** *Dependent upon local conditions and whether water treatment systems are installed and operated, additional monitoring of water characteristics, such as suspended or dissolved solids, and contaminants may be required.*

b. **Water Temperature.** VHA requirements for water temperature limits for *Legionella* control in the building's potable hot and cold water distribution systems are as follows:

(1) **Hot Water Distribution Systems.** If a building uses domestic hot water storage tanks, water temperature of all such storage tanks must be maintained at a minimum of 140 degrees Fahrenheit (°F) (60 degrees Celsius (°C)) to prevent *Legionella* growth. The minimum discharge temperature for instantaneous and semi-instantaneous heat

exchangers must be 130°F (54.4°C). Water in the potable hot water distribution system piping must be no lower than 124°F (51.1°C) (prior to any temperature-reducing mixing valve or anti-scald device at the water outlet). ***NOTE:*** *To limit the risk of scald injury, hot water in the distribution system piping must be maintained at the lowest temperature that will ensure the minimum of 124°F (51.1°C) throughout.*

(2) **Cold Water Distribution Systems.** *Legionella* can grow in the building's cold-water distribution system as water temperatures increase above 67°F (19.4°C). Cold water temperature throughout the system must be maintained at or below 67°F (19.4°C) to the greatest extent practicable to inhibit growth. ***NOTE:*** *Use of piping system insulation, automatic drain devices and recirculation can limit the rate and duration of increased temperatures within the cold water distribution system. Based on local conditions and validation testing, modifications or upgrades of the cold-water distribution system may be required.*

(3) **Water Temperature Monitoring.** The water temperature in the hot and cold potable water distribution systems must be monitored continuously to ensure temperatures are within the established control limits. Temperature monitoring must be conducted, at a minimum, in the following areas: incoming water supply to the building, water storage tanks, discharge from hot water source equipment, water at the return of circulation loops and water supplied to representative areas of the building (e.g., top of risers, hydraulic remote points in loop or branch).

(a) Water temperatures at points of continuous monitoring must be reviewed on a routine basis (minimum of weekly) to determine if they are in the defined control limit range or if corrective actions are needed.

(b) Document when the water temperature monitoring results are reviewed and what actions were taken, if any.

(4) **Water Temperature Control at the Outlet.** Buildings subject to this directive must minimize the risk of scald injury to patients, residents, staff and visitors. The use of mixing valves on all outlets where people access hot water is required to prevent scald injury. The water temperature delivered from the outlet must not exceed 110°F (43.3°C). See Appendix B for specific requirements and guidelines for the prevention of scald injury.

c. **Biocide.** Oxidizing agents have long been utilized by municipal water treatment facilities for inhibiting bacterial growth in public water supplies. Implementing systems in building water distribution systems to deliver biocides can be effective in inhibiting bacterial growth, particularly if biocide residual in incoming water is low; however, their operation requires careful oversight for effective and safe use. For all buildings subject to this directive, the following paragraph includes the requirement to assess the quality of incoming water and requirements if a VA medical facility decides to implement biocide-based water treatment system(s) in such buildings.

(1) **Incoming Water.** Biocide residual levels in the building incoming water supply and at representative outlets must be assessed. This assessment will determine if any biocide from the municipality or other potable water source is present when the water reaches the building and after distribution in the building. Knowing these values will aid in determining if biocide residual levels are at a sufficient level to suppress *Legionella* growth (if present) and will contribute to the information available if deciding whether or not to install a potable water treatment system(s) or make changes or updates to the system to improve levels. Monitoring the biocide residual level in the incoming water supply must be continual.

(2) **Building Water Distribution System.** Minimum concentrations of biocide residual necessary for inhibition of *Legionella* growth may vary from building to building. In general, the following minimum detected biocide residual levels at hot and cold-water outlets are suggested as guidance: 0.5 milligrams (mg) per liter (L) for chlorine (as free chlorine), 0.5 mg/L for monochloramine and 0.3 mg/L for chlorine dioxide. ***NOTE:*** *These concentrations are considered guidance. VA medical facilities may find that higher or lower levels are needed for* Legionella *growth inhibition in their building(s) based on local conditions and environmental testing for* Legionella*.*

(a) Monitoring the biocide residual in water supplied to representative points in the system must be continual (e.g., riser, loop or branch, hydraulic remote point). The continuous measurements must be reviewed on a routine basis (minimum of weekly) to determine if they are in the defined control limit range or if corrective actions are needed. Document when the biocide monitoring results are reviewed and what actions were taken, if any.

(b) Irregularly used or low flow fixtures must be flushed at least twice per week to prevent water stagnation (see paragraph 3.d. of this Appendix).

(3) **Potable Water Treatment.** VA medical facilities may choose to implement a potable water treatment system(s) in buildings to supplement municipal or source treatment of water. Factors to consider for this decision include but are not limited to: the levels of biocide residual in the incoming water supply and at outlets; past history of HCA LD; and results from environmental and clinical validation testing (see Appendix C). If the VA medical facility decides to install a treatment system in a building, then the following actions are required:

(a) Any biocides for use in potable water treatment systems must be specifically approved or recognized for the intended use by the State regulatory water authority or provided recognition in writing that a permit is not required and the product can be used for the intended purpose. VHA recognizes U.S. Environmental Protection Agency approved oxidants (chlorine, chloramine and chlorine dioxide) as acceptable disinfectants for use in potable water distribution systems. Use of an alternative biocide is permitted if the VA medical facility obtains a waiver (subject to its conditions and duration). ***NOTE:*** *Waiver process information and requirements will be provided by HEFP*.

(b) The Facility Water Safety Committee must determine the appropriate type of treatment system for the building. The VA medical facility must consult with the State (or its delegated local water authority) office for regulating drinking water for guidance on system selection, achieving an appropriate biocide residual level at building outlets for *Legionella* growth suppression, system design, system operation and ensuring compliance with regulations regarding water treatment system(s) and safety (see 40 Code of Federal Regulations (C.F.R.) Parts 141-142).

(c) In addition, the VA medical facility must evaluate the interaction between different chemicals and how they affect one another (e.g., potable water treatment system with monochloramine and remediation with chlorine). Once a type of system is selected, either the State (or its delegated local water authority) or the manufacturer of the system must provide the minimum and maximum outlet biocide levels in writing for both hot and cold water. ***NOTE:*** *See paragraph 5 of this appendix regarding special-use water systems.*

(4) **Biocide Residual Monitoring.** The biocide residual levels of the water at distal water outlets in the hot and cold potable water distribution systems must be monitored to determine if levels are within the established control limits and in compliance with regulatory requirements. In addition, they must comply with regulatory requirements for contaminant level monitoring frequency and locations, as defined in permit to operate for supplemental systems. Testing must be documented and executed per the regulatory body for this monitoring, which may differ from the requirements of this document. If the regulatory body does not require a permit, the site must monitor as though a permit was required (consult with HEFP on this issue for guidance).

d. **Corrective Actions.** If routine monitoring determines that the water temperatures or biocide residual levels in the system are not within the established limits in the HCA LD Prevention Plan, then the following actions, at a minimum, must occur:

(1) Assess the reason(s) why the control(s) were not within the established limit.

(2) Promptly implement corrective actions or modifications to the engineering controls based on the assessment to ensure control measures are within established limits.

(3) Re-assess the engineering controls after corrective actions/modifications are implemented to determine if the action corrected the deviation and system is operating at the established limits. If not within the established limits, reassess the corrective actions and implement revised corrective actions.

e. **Documentation.** Water temperature and biocide residual testing, as well as corrective actions, must be documented to provide verification of implementation and monitoring.

f. **Validation of *Legionella* Prevention.** Validation focuses on collecting and evaluating information to determine if the engineering controls are effectively controlling *Legionella* growth in the building's potable water distribution systems. See Appendix C

for the validation requirements, which include both a clinical component to assess incidence of HCA LD and an environmental component to assess the presence of *Legionella* in the water distribution system.

3. SUPPLEMENTAL ACTIONS

Until the primary prevention strategy (i.e., biocide treatment system if chosen and water temperature) is implemented fully, supplemental actions may be necessary to assess or prevent *Legionella* growth in building water distribution systems based on local conditions and validation results. ***NOTE:*** *If a building meets the primary prevention requirements, the VA medical facility also may choose to implement these supplemental actions based on local considerations.*

a. **Environmental Water Testing for *Legionella*.** VA medical facilities may consider increasing the frequency of environmental water testing for *Legionella* during the year beyond the testing frequency required in this directive (see Appendix C). VA medical facilities also may consider increasing the number of samples taken during a testing cycle, based on local risk assessment (e.g., history of HCA LD, patient population, ability to implement engineering controls, size of building) to determine if additional control procedures need to be implemented.

b. **Supplementary Water Treatment Measures.** Supplementary treatment measures are measures that suppress *Legionella* growth and minimize the risk of exposure such as remediation, remediation of part of the water distribution system or remediation of equipment. Supplementary measures need to be identified in the building plan and schematic diagrams and control limits identified. The systems must be monitored and adjusted in a timely manner, if indicated, to ensure operation at a capacity to inhibit the growth of *Legionella*. Documentation of system verification and maintenance activities is required.

c. **Point-of-use Filters.** Point-of-use filters that prohibit passage of bacteria (0.2 micron or finer) may be installed at specific outlets to prevent *Legionella* exposure to patients. This method may be of particular use in areas that treat high-risk patients.

d. **Flushing.** The purpose of routine flushing is to prevent stagnating conditions in pipes which could result in tempering of water temperature, dissipation of biocide and establishment of favorable conditions for *Legionella* growth. Regular flushing of hot and cold water at outlets (e.g., sink taps, showers), particularly those not in routine use, or which experience low water usage, is necessary to ensure that engineering controls are maintained at sufficient levels to mitigate *Legionella* growth in the water distribution systems and at fixtures. Irregularly used or low flow fixtures must be flushed at least twice per week to prevent water stagnation. If this method is used, there must be policy and procedure in place and documentation of execution to ensure compliance.

4. REMEDIATION OF THE POTABLE WATER DISTRIBUTION SYSTEMS.

Remediation of a building's potable water distribution system(s) can be triggered by certain occurrences such as: identification of a presumptive HCA LD case; identification

of a possible HCA LD case and *Legionella*-positive water results; or identification of *Legionella*-positive water results during routine environmental testing. See Appendix C for specific requirements and detailed information for assessing, at a minimum, when remediation is to be conducted and to what extent.

a. Remediation includes one or both of the following immediate actions. The Facility Water Safety Committee must determine which action(s) to take and to what extent for the following:

(1) **Thermal Remediation.** This procedure involves the temporary resetting of the temperature in the hot water distribution system(s) to 160°F - 170°F (71°C - 77°C) and then continuously flushing each outlet in the system for at least 30 minutes. The water at each outlet must be at 160°F - 170°F during the flushing period for thermal remediation implementation to be considered complete. Consideration needs to be given as to the feasibility of implementing thermal remediation depending on the design of the mixing valves in place. ***NOTE:*** *Since there is significant risk for scalding at the water temperatures used for thermal remediation, extreme care must be taken to protect end users of the water distribution system(s), as well as employees who are administering the measure.*

(2) **Hyper-chlorination.** This method involves injecting chlorine (i.e., sodium hypochlorite) at an elevated level in the hot and/or cold-water distribution systems to at least 2 mg/L and maintaining that level throughout the systems for at least 2 hours (but not exceeding 24 hours) and flushing all outlets. Hyper-chlorination of the hot water tank(s) or the water heater(s) at a higher level due to their size and capacity may be required to achieve this level of free chlorine residual. After the hyper-chlorination procedure is complete, the system must be thoroughly flushed to reestablish the normal operating level before reuse. If water testing after hyper-chlorination indicates that *Legionella* bacteria are still present in the water distribution system(s), it may be necessary to repeat hyper-chlorination with consideration for use of a higher concentration of chlorine (e.g., at least 10 mg/L free chlorine residual throughout the system and at outlets for 24 hours). Use of very high concentrations of chlorine (e.g., 200 mg/L) for *Legionella* remediation should not be a first resort. Consultation with HEFP is required for implementation of chlorine levels higher than 10 parts per million (ppm). ***NOTE:*** *Thermal remediation and hyper-chlorination are temporary measures.* Legionella *will likely reappear if proper routine water temperatures or residual biocide levels (or other supplementary actions or processes) are not maintained.*

b. After remediation is complete and the system is back to normal operating levels, perform environmental testing for *Legionella* detection to determine the effectiveness of the mitigation action. ***NOTE:*** *Wait at least 24 hours after the remediation process is complete before collecting environmental samples for* Legionella *testing.*

c. Prior to the implementation of remediation, the VA medical facility occupants must be informed that this process will take place in order to facilitate safe implementation of the procedures. After the remediation process is complete, communication must occur

to inform building occupants that the water is acceptable for general use. The VA medical facility must document any remediation processes that take place.

5. SPECIAL USE WATER SYSTEMS

It is important to consider the implications of *Legionella* control and remediation strategies on special use water systems (e.g., hemodialysis, laboratory) within the building. For example, chemical disinfectants may result in the introduction of products into, or the formation of disinfection byproducts in, the building water supply at concentrations that may be toxic to patients on hemodialysis. Accordingly, the impact of control and remediation strategies must account for potential toxicity, methods for removal of the chemical agent and byproducts from the special use water system and the availability of assay methods to measure the chemical agent and byproducts for assuring patient safety. Employees responsible for the oversight of special use water systems are to be consulted during the development and implementation of water treatment strategies for *Legionella* and promptly notified of any changes in treatment procedure.

POLICY AND GUIDELINES FOR MINIMIZING THE RISK OF SCALD INJURY FROM EXPOSURE TO HOT WATER FROM THE POTABLE HOT WATER DISTRIBUTION SYSTEM

1. INSTALLATION OF ANTI-SCALD DEVICES AND MIXING VALVES

One of the primary methods for preventing *Legionella* growth in building potable water distribution systems is water temperature. However, it is not possible to maintain water temperatures at the outlet that kill *Legionella* bacteria (124 degrees Fahrenheit (°F) or greater) and simultaneously eliminate the possibility of scald injury in persons partially or fully insensitive to hot water temperature, or having delayed or impaired response capabilities. For most adult individuals, 110°F at the water outlet (e.g., sink tap, showerhead) will minimize the risk of scalding and is consistent with the plumbing code adopted by Department of Veterans Affairs (VA) for Veterans Health Administration (VHA) buildings. At 117°F, the risk of scalding increases significantly. At 140°F, second degree burns may occur after only 3 seconds of exposure. Some people, either due to illness, disabilities, extremes of age or side effects of medication may be less sensitive to hot water temperatures or have impaired or reduced reactions, and thus, are at an increased risk for tissue damage caused by extended exposure to hot water.

a. **Requirement.** To allow for circulating hot water temperatures at a level that inhibits *Legionella* growth, buildings subject to this directive (see paragraph 1. in the body of this directive) must install mixing valves (can be supplemented with anti-scald devices) at all outlets to regulate the temperature of water and prevent scalding where end users access water (e.g., sink taps, showers). Mixing valves are to be positioned as close to the outlets as possible, thus allowing for increased hot water temperatures in a greater portion of the building potable hot water distribution system(s) at a temperature that will kill *Legionella* or inhibit growth.

b. **Water Temperature.** Mixing valves are to regulate water temperature so that water is discharged from outlets at 110 °F or below. ***NOTE:*** *Water temperature for emergency showers and eyewashes must be between 60°F and 100°F.*

c. **Selection of Temperature Regulating Devices.** The VA medical facility is to determine the type(s) of mixing valve that will be installed in accordance with VA Plumbing Design Manual/Master Construction Specifications (https://www.cfm.va.gov/til/) and the International Plumbing Code. ***NOTE:*** *Use of mixing valves may result in water temperature between the mixing valve and the end use point (outlet) at a temperature conducive to* Legionella *growth. Maintaining biocide residual levels at these sites (e.g. with an installed system and/or with periodic flushing) can inhibit* Legionella *growth. Results from environmental (validation) testing for* Legionella *can identify areas that may need supplemental attention.*

d. **Inspections.** Anti-scald devices and mixing valves must be tested and serviced for proper functioning at least annually and in accordance with manufacturers' instructions. More frequent inspections and maintenance of devices and valves may be required, based on the quality of water. Inspections and any performed maintenance must be documented.

2. EQUIPMENT WHERE PATIENTS ARE EXPOSED TO HEATED WATER VIA FULL OR PARTIAL IMMERSION

a. For equipment where patients are fully or partially immersed in heated water (e.g., bathtubs, whirlpool tubs and foot baths), the following measures are required to prevent scald injury.

(1) Mixing valves at the outlet that are capable of blending the hot and cold-water supply to hold water temperatures at or below 110°F are required. ***NOTE:*** *Maximum temperature of water outflow may be reduced based on a risk assessment of users or settings (e.g., Spinal Cord Injury/Disorder Center, Community Living Center).*

(2) All patient immersion baths must be equipped with a large digital readout device displaying the bath water temperature. Bath water must not exceed 110°F at the time of patient immersion. The readout temperature must be verified by taking the temperature of the water with a hand-held thermometer (preferably non-mercury containing) and comparing this reading with the reading of the tub thermometer. For tubs with an elevated reservoir tank, a remote temperature-sensing probe that can be submerged into the tank water may be utilized to provide the verification temperature. Thermometers and probes must be calibrated, used and validated in accordance with manufacturers' instructions. ***NOTE:*** *Using sensation alone (e.g., hand, wrist, elbow) is not an acceptable practice for determining safe water temperature.* The actual temperature of water in the tub must be accurately monitored before and during each bath. Consideration needs to be given to the documentation of these temperatures. VA medical facilities must determine an acceptable range of temperature for patient immersion baths that do not exceed the maximum limit of 110°F.

3. IMPLICATIONS FOR IMPLEMENTATION OF THERMAL REMEDIATION

Thermal remediation (i.e., the raising of the hot water temperature to 160°F - 170°F and the flushing of outlets; see Appendix A, paragraph 4.a.(1)) is an option for remediation of *Legionella* in hot water distribution systems. If the VA medical facility prefers to have the thermal remediation option available, then selection of anti-scald devices and mixing valves that can operate in the conditions required is recommended. Alternatively, a VA medical facility could use a different *Legionella* remediation option, such as hyper-chlorination on its own or in conjunction with thermal remediation (to the extent feasible with mixing valves present).

CLINICAL AND ENVIRONMENTAL VALIDATION OF ENGINEERING CONTROLS FOR PREVENTION OF *LEGIONELLA* GROWTH IN BUILDING POTABLE WATER SYSTEMS

1. BACKGROUND

Validation focuses on collecting and evaluating information to determine if the engineering control measures (e.g., water temperature, biocide levels) are effectively controlling *Legionella* growth in a building's potable water distribution system(s). The two validation methods for Veterans Health Administration (VHA) buildings subject to this directive (see paragraph 1 in the body of this directive) are clinical surveillance testing and environmental water testing. Validation procedures are to be included in the building health care-associated (HCA) *Legionella* disease (LD) prevention plan. Requirements for the two methods are described in paragraphs 2 and 3 of this appendix, along with guidance on interpretation of results and remedial actions. Summary flow charts depicting the key concepts for environmental validation and clinical validation are included at the end of this appendix. ***NOTE:*** *While environmental water testing is listed first in this appendix for logistical reasons, it is not meant to imply priority or importance over the clinical surveillance for disease. Furthermore, both the clinical and environmental validation processes in this appendix are intended to assess the effectiveness of the routine implementation of engineering controls and may not include all practices necessary after a case of HCA LD or in an outbreak situation.*

2. ENVIRONMENTAL VALIDATION

For this appendix, environmental validation is the process of periodically testing the building's potable water distribution system(s) to determine if the engineering controls are successfully inhibiting growth of *Legionella*. Therefore, the primary use of the findings from this routine environmental testing is to assess if adjustments to the implementation of the engineering controls are necessary. However, since *Legionella* in the water system of a health care building may be a risk for building occupants, this section provides overarching requirements and recommendations for both assessment of engineering controls and remedial actions. ***NOTE:*** *See paragraph 5 of this appendix for a summary flow chart for interpreting routine water testing results.*

a. **Quarterly Testing Requirement.** Testing of the building's water distribution system(s) for *Legionella* must be performed at least quarterly (once per Federal Fiscal Year quarter).

(1) At least 20 water samples (first draw) from water outlets from each building must be tested for *Legionella* for each quarterly testing cycle. After taking the *Legionella* water sample, take additional samples at the same outlet to test and document water temperature, pH and level of biocide. ***NOTE:*** *Department of Veterans Affairs (VA) medical facilities may choose to conduct testing of additional outlets or areas beyond the required 20 outlets (e.g., water tanks, distribution piping). This additional testing*

must be determined based on local conditions (e.g., size of building, patient population risk factors, known history of HCA LD, suspicion for recent or current HCA LD occurrence, previous environmental testing results, unique aspects of the VA medical facility's infrastructure and ability to implement engineering controls to prevent Legionella growth in the building water distribution systems). Additional information on how to test water samples is available at the Water Safety Management and Legionella Resources website at http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA website that is not available to the public. The types of water samples to be collected for testing are as follows:

(a) At least two of the 20 samples must be from an ice machine or other pure cold-water source. ***NOTE:*** *Ice machines have been implicated as a source for HCA LD in outbreak investigations reported in the literature. Ensure all ice machines used for patient or resident care are properly maintained and cleaned on a routine basis.*

(b) At least two of the 20 samples must be from a pure hot water source (i.e., no mixing valve present), if such water outlets are available.

(c) For the remainder of the samples, where a mixing valve is in place at the outlet, the first draw sample is considered a mixed hot/cold ("mixed") water sample. If no mixing valve is in place at the outlet, take the first draw sample from either the hot or cold side. The distribution of hot, cold and mixed water samples from a building for each quarterly testing cycle is dependent on the types of outlets and mixing valves present. Representation from each type of water sample available (hot, cold and mixed) must be attempted each quarter based on the building risk assessment, past testing results and deliberations of the Facility Water Safety Committee to determine where validation testing is most needed.

(d) For buildings with 20 or fewer sample locations, testing of 50% of the potential sample locations can be done each quarter instead of all 20 samples each quarter. The location of the samples must be varied during each sampling cycle, as should the types of water samples taken (hot, cold and mixed) based on deliberations of the Facility Water Safety Committee and validation needs.

(2) For routine water testing, collection of swab samples is not required, although a VA medical facility may choose to collect swab samples in addition to water samples. Swab samples alone do not meet the requirement of this directive.

b. **Laboratory Requirements.** Once collected, samples are to be processed for *Legionella* detection by a testing laboratory with experience in microbial testing of potable water. In addition to culture methodology for *Legionella* detection, VA medical facilities may choose to first have water samples tested by polymerase chain reaction (PCR) to screen for negative samples (see paragraph 2.c. of this Appendix for more details). The testing laboratory is to be selected, with input from the Facility Water Safety Committee, using the following criteria:

(1) Laboratories that process water samples for microbiological testing must:

(a) Be accredited by a recognized regional, national or international accrediting body as follows:

1. In accordance with a laboratory accreditation standard (e.g., ISO/IEC 17025: 2017, General Requirements for the Competence of Testing and Calibration Laboratories). Examples of such accrediting bodies include the National Environmental Laboratory Accreditation Program (NELAP); the American Association for Laboratory Accreditation (A2LA); and the Environmental Microbiology Laboratory Accreditation Program (EMLAP).

2. Include *Legionella* testing method(s) that will be used on facility water samples in the laboratory's scope of accreditation, as documented on the laboratory's accreditation certificate.

(b) Demonstrate proficiency by the Centers for Disease Control and Prevention (CDC) Environmental *Legionella* Isolation Techniques Evaluation (ELITE) program or the Public Health England (PHE) *Legionella* External Quality Assessment (EQA) scheme at performing the culture of *Legionella* from environmental samples. Information about the CDC ELITE program and a listing of laboratories that are ELITE members can be found at https://wwwn.cdc.gov/elite/public/elitehome.aspx. If PCR will be used in addition to culture, then the laboratory also must demonstrate proficiency at PCR detection of *Legionella* from environmental samples by the CDC-recognized lab conducting proficiency testing (currently the Wisconsin State Laboratory of Hygiene (WSLH)) or by the PHE EQA *Legionella* molecular scheme. ***NOTE:*** *The method(s) used by the laboratory on the samples that the VA medical facility uses to determine* Legionella *positivity is to be the same method(s) used by the laboratory for proficiency testing.*

(c) Be able to determine if the *Legionella* detected by culture in environmental samples is the species *Legionella pneumophila* and, if so, if it is *L. pneumophila* serogroup 1.

(2) If there is a possibility that the VA medical facility will use molecular typing to characterize environmental *Legionella* isolates (e.g., for potential comparison to clinical *Legionella* isolates during a case investigation), then the VA medical facility must make arrangements with the testing laboratory for storage of the environmental isolate(s) at least temporarily.

(3) Prior to environmental testing, the selected laboratory must be consulted regarding requirements and recommendations on sample collection and shipping. Protocols recommended by the laboratory must be in alignment with the requirements in this directive. ***NOTE:*** *The selected laboratory must be informed if biocides (e.g., chlorine) have been added to the building's potable water distribution systems to determine if samples must be processed to neutralize the biocide prior to being sent out for testing.*

c. **Optional Use of *Legionella* PCR to Screen Water Samples ("PCR Negative screen").** The PCR method detects the presence of *Legionella* genetic material in water samples. Detection of *Legionella* genetic material indicates the presence of *Legionella* in the water sample, though the method may not be able to determine reliably if the *Legionella* are alive or dead. Therefore, VA medical facilities may opt to use *Legionella* PCR testing to first determine if water samples are negative for the detection of *Legionella* genetic material. ***NOTE:*** *The PCR method utilized must be able to detect the genus* Legionella*, not just* L. pneumophila*.* If a water sample is negative by PCR, then further processing of that sample by culture is not required and the sample can be considered "negative for *Legionella* detection". If the sample is positive by *Legionella* PCR or if the laboratory reports the PCR result as indeterminate, then that same water sample must be processed for culture detection of *Legionella* to determine if living *Legionella* are present; the culture result is then used to determine if the sample is *Legionella*-positive or not. The following criteria must be considered by the Facility Water Safety Committee when determining if the PCR negative screen will be utilized:

(1) The PCR test is to be done by a laboratory that is accredited and deemed to be proficient to detect *Legionella* in water samples by PCR. ***NOTE:*** *Use of point-of-use PCR kits that do not meet the laboratory requirements in this appendix is not permitted.* Confirm with the testing laboratory that the PCR test will be completed with results reported in a timely manner after receipt of the sample and that the sample will be stored appropriately while PCR testing results are pending in case the sample will need to be processed by culture.

(2) The optional use of this PCR negative screen must be assessed on a building level. When deciding if this PCR option will be utilized for a building, it may be prudent to consider whether routine water testing for the building has been habitually negative, and the costs associated with the test. ***NOTE:*** *The cost effectiveness of using the PCR negative screen is determined at the VA medical facility level.*

(3) For samples that are *Legionella*-positive by PCR, the following requirements apply:

(a) The PCR-positive water sample must be processed by a culture method (in accordance with laboratory selection criteria) to confirm living *Legionella* are in the sample. While some PCR tests claim ability to differentiate between living and dead *Legionella*, such designations are not sufficiently reliable and use of the PCR result to determine that the *Legionella* are living is not permitted.

(b) While the results of the culture tests are pending, the following action is required: assess the implementation of the engineering controls (e.g., water temperature, biocide levels) to determine if corrective adjustments need to be made.

(c) If the culture result of a PCR-positive sample is subsequently positive, follow the actions in paragraph 2.d. of this Appendix.

d. **Interpretation of *Legionella* Culture Results from Water Testing.** If no *Legionella* are detected in all routine water samples, then the quarterly validation cycle is complete. If *Legionella* are detected by culture in at least one sample then there are three different sets of actions that are required: assessment of routine engineering controls, remediation requirements and considerations, and clinical validation. ***NOTE:*** *For subsequent clinical validation actions related to* Legionella*-positive environmental samples, see paragraph 3 of this appendix. See paragraph 5 of this appendix for a summary flow chart for interpreting routine water testing results.*

(1) **Assessment of Routine Engineering Controls.** If environmental testing detects any amount of *Legionella* (any species) by culture, then the actions in this sub-paragraph are required. ***NOTE:*** *The* Legionella *results must be evaluated on at least a building level since each building may have specific considerations to assess and improve implementation of controls.* Assess the implementation of the engineering controls (e.g., water temperature, biocide levels) in the area(s) of the positive sample(s) to determine if corrective adjustments must be made. It is particularly important to assess and adjust implementation of engineering controls if the extent of *Legionella* colonization (e.g., percentage of positive outlets) or concentration of *Legionella* detected is high, or if the extent of *Legionella*-positivity or *Legionella* concentration has increased compared to previous quarters, since these findings could indicate that conditions in the water system are conducive to *Legionella* proliferation. ***NOTE:*** *Assessment of engineering controls is a critical, primary response step since the purpose of routine* Legionella *testing is to validate that routine engineering controls are inhibiting* Legionella *growth.*

(2) **Remediation.** This section describes the minimum actions required to mitigate potential risk after detecting *Legionella* in building water distribution systems during routine testing. ***NOTE:*** *VA medical facilities may choose to implement more stringent actions. This is a local decision based on building risk assessments. For example, a building with a history of HCA LD at any time in the past may require remedial actions to be taken regardless of type or concentration of* Legionella *detected.*

(a) Implement remedial action using the criteria in paragraph 2.d.(2)(b) of this appendix if environmental testing detects *L. pneumophila* at a concentration of one colony forming unit per milliliter (CFU/ml) or greater. This remedial action approach uses a “graded response” for addressing *L. pneumophila*-positive samples detected through routine water testing. That is, while each positive sample will require further assessment, the extent of remediation is situation dependent.

1. For areas of the building with individuals considered at higher risk for infection (e.g., transplant units, protective environments, hematology-oncology units), if environmental testing detects any amount of *Legionella* (any species), then follow the requirements in paragraph 2.d.(2)(b), below (graded response for remediation). Consider whether other actions need to be taken to reduce the risk of exposure to *Legionella* until the remediation process is complete (e.g., moving of patients, use of point-of-use filters and use of bottled water).

2. For areas of the building not considered to be higher risk, if the *Legionella* detected was not *L. pneumophila* or was *L. pneumophila* at less than 1 cfu/ml, then the Facility Water Safety Committee must determine what additional actions, if any, will be taken. The committee must consider the following factors when determining if remediation will be implemented using the graded response in paragraph 2.d.(2)(b) of this appendix:

a. Comparison of results to past quarters of testing to determine if the area is habitually positive for *Legionella* pneumophila, even at levels below 1 cfu/ml. ***NOTE:*** *The committee may choose to have more testing done in the area(s) if more data could be helpful in making a decision.*

b. Comparison of results to past quarters of testing to determine if there is an increase in the extent of positivity regardless of *Legionella* species. That is, assess whether the data indicate that *Legionella* are proliferating in the water system. For example, this could be indicated by an increase in the percent of water samples in which *Legionella* were detected or an increase in the concentration of *Legionella* in water samples.

(b) The minimum remedial actions required to mitigate potential *Legionella* risk (i.e., the "graded response") are as follows:

NOTE: *The water system(s) to be remediated is determined by the types of water samples that were considered positive. If the positive results were from pure cold-water samples or pure hot water samples, then remediate the corresponding water distribution system (hot, cold or both). If the positive results were from mixed hot/cold samples, then the minimum requirement is to remediate the hot water distribution system; the Facility Water Safety Committee must determine if remediation of the cold water distribution system is also needed (e.g., based on additional testing or knowledge from past environmental testing results of hot versus cold water positivity).*

1. If one water sample is determined to be positive, then, at a minimum, the fixture that tested positive must be promptly remediated by chlorinating the fixture and supply lines. Review past routine testing results in the area of the positive fixture to determine if more extensive remediation may be beneficial. ***NOTE:*** *A VA medical facility may choose to conduct additional testing in the area of the positive fixture to determine if more extensive remediation is needed.* Retest the outlet after remediation is complete to determine if the remediation was successful. If the remediation was successful, then the quarterly environmental validation cycle is complete. If the remediation was not successful at reducing *Legionella* positivity, assess the remediation procedure and repeat remediation and retesting until the remediation is successful. ***NOTE:*** *When re-testing the water after remediation, wait at least 24 hours after remediation is complete before taking the water samples. This re-testing as post-remediation follow-up is not to be considered as a sample for the next round of routine quarterly environmental testing.*

2. If more than one water sample is considered positive, assess the results to determine the subsequent actions as follows:

a. If the water samples that tested positive are in the same area of the building or on the same water distribution loop, then promptly conduct remediation of the area or loop.

b. If the water samples that tested positive are in different areas of the building or on different water distribution loops, then promptly conduct remediation in a graded response based on location of the positive outlets. The Facility Water Safety Committee must meet to review the location of the positive water samples in relation to the configurations of the building water distribution system(s) to determine the extent of remediation (i.e., fixture, areas/loops versus the entire building). For example, if there are two positive sample results in different parts of the building and all other samples are negative, then the VA medical facility may determine that targeted remediation of each fixture is appropriate, or that remediation of those areas or loops with positive samples is appropriate (e.g., based on results from past quarters). If multiple outlets are positive throughout the building, then the VA medical facility must consider remediation of the entire water distribution system(s) in the building as described in Appendix A, paragraph 4. Detection of *L. pneumophila* in more than one outlet in different areas of the building water system on repeated cycles of routine quarterly water testing is also a strong indication for remediating the whole system. VA medical facilities must consider local factors (e.g., previous environmental testing results; VA medical facility size and configuration of water distribution systems; population risk factors; and past history of HCA LD) when determining the extent of remediation to be conducted. ***NOTE:*** *The overarching goal is to use* Legionella *testing data to try to understand whether the pathogen is being controlled in the system and, if not, to what extent the data indicate that proliferation is occurring. Mitigating the risk of these validation results must be assessed on a case-by-case basis. Consultation from the Office of Healthcare Engineering (OHE) and the National Infectious Diseases Service (NIDS) is available for assistance with assessing validation testing results.*

c. After remediation is completed, retest the water in the areas that tested positive to determine if the remediation procedures were successful. If the remediation procedures were successful, then the quarterly water environmental validation cycle is complete. If the remediation procedures were not successful, assess the post-remediation results for location of positive samples, assess the remediation process and repeat remediation and retesting until remediation is successful. ***NOTE:*** *When re-testing the water after remediation, wait at least 24 hours after remediation is complete before taking the water samples. This re-testing of the water distribution system(s) for* Legionella *as post-remediation follow-up must not be considered as samples for the next round of routine quarterly environmental testing.*

d. Documentation is required for environmental testing (e.g., date, outlets and results), any assessments of positive results, any remedial action taken and efficacy of remedial actions. ***NOTE:*** *Discussion of environmental testing findings and remedial actions must be a component of the quarterly Facility Water Safety Committee meetings as described in paragraph 5.m.(7)).* An annual summary report of these items must be submitted to the VA Medical Facility Safety Committee and Infection Control Committee.

e. **Reporting Environmental Testing Results.** VA medical facilities are required to report environmental testing results, taken in accordance with *Legionella* testing requirements in this directive, to the VHA Water Safety Management Tool (WSMT) database or equivalent. The WSMT database can be found at: http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. ***NOTE:*** *This is an internal VA website that is not available to the public. Further, this requirement pertains to the reporting of samples taken specifically for* Legionella *testing, including related readings such as biocide levels and water temperature. This requirement does not pertain to the reporting of routine or continual engineering control monitoring; those results must be recorded locally to monitor the implementation of controls.*

(1) The required content, VISN Water Safety Liaison validation, frequency and timeframe for reporting results to the WSMT must be in accordance with the database User Manual. ***NOTE:*** *The WSMT User Manual can be found on the VHA Water Safety Management & Legionella Resources intranet site at: http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA website that is not available to the public.*

(2) Reporting of environmental *Legionella* testing results is required for samples taken for any component of this directive, such as routine testing, post-remediation testing, or investigation of an LD case or cases.

(3) No clinical *Legionella* data are to be reported using the WSMT. Reporting of clinical *Legionella* data is to follow the requirements in the directive (paragraphs 5.g.(8)(a) and 5.g.(8)(b)).

3. CLINICAL VALIDATION

Clinical validation is the process of determining if the primary engineering controls and any supplemental actions are successfully inhibiting *Legionella* growth in the potable water distribution system(s) by monitoring the occurrence of HCA LD in VHA patients and residents. Although monitoring of visitors and employees for LD is not within the scope of clinical practice, learning that a visitor or employee is diagnosed with LD and had exposure to the VA medical facility is information that must be considered for assessment of engineering controls and need for further action. ***NOTE:*** *This directive focuses on prevention of HCA LD. If a case of HCA LD is detected, this directive provides policy for immediate actions to prevent further cases. Guidance for case investigations of confirmed or suspected HCA LD is available from the CDC at:https://www.cdc.gov/legionella/health-depts/healthcare-resources/cases-outbreaks.html. Consultation with the VHA National Infectious Diseases Service is available if assistance is necessary. See paragraph 6 of this appendix for a summary flow chart for Clinical Validation.*

a. **Clinical Testing.** Consider diagnostic *Legionella* testing for patients or residents who have pneumonia (community- or health care-associated); such testing is to be conducted if clinically indicated. Diagnosis of LD relies principally on use of *Legionella*

urinary antigen testing which detects disease caused by *L. pneumophila* serogroup 1. Culture of sputum or other respiratory specimens for *Legionella* is also to be considered if these types of clinical specimens are collected during the course of clinical management of the case. If a case of LD is diagnosed, see paragraph 3.c. of this appendix to determine if there is a link of the case to the VA medical facility.

(1) If there are known cases of LD in the community (e.g., at other health care facilities in the surrounding area, from a known higher incidence of LD in the geographic area or alerts from the local Health Department) then it would be prudent to maintain a high index of suspicion of LD for patients that present to the VA medical facility with pneumonia.

(2) It would be prudent for clinical staff at the VA medical facility (e.g., infection prevention and control) to periodically assess whether patients with pneumonia, especially HCA pneumonia, are being tested for LD. This is especially important when conditions at the facility indicate the need for heightened awareness for clinical testing (see paragraph 3.b. of this Appendix). ***NOTE:*** *Additional information on clinical diagnosis of patients with pneumonia for LD can be found at the VHA Water Safety Management and* Legionella *Resources intranet site located at: http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal website and not available to the public.*

b. **Circumstances for Heightened Awareness for Clinical Testing.** If *Legionella* is found during environmental validation testing, clinicians are to be vigilant for patients who develop respiratory disease or processes suggestive of pneumonia (e.g., fever with cough or production of sputum or radiographic findings) during their hospital admission or while under residential care, and perform testing of such identified patients for LD. Clinicians also must have heightened awareness for clinical testing if a case of presumptive or possible HCA LD is detected for the building or if there is a community-based outbreak of LD. ***NOTE:*** *For the situation in which environmental testing indicates positive* Legionella *results, the results must be communicated to clinical providers in order to initiate heightened awareness for clinical testing (see paragraph 4 of this appendix). If the* Legionella *detected during environmental water sampling is* L. pneumophila *serogroup 1, then use of both urinary antigen testing and sputum culture for diagnosis of LD is appropriate. If* Legionella *other than* L. pneumophila *serogroup 1 is found during the environmental water sampling, then use of sputum culture for diagnosis of LD is appropriate; it is also reasonable to consider urinary antigen testing in addition to culture testing since* L. pneumophila *serogroup 1 may also be present in the water distribution system.*

(1) This heightened state of clinical vigilance and testing as a result of positive environmental samples must be followed for at least 3 months and until the next round of quarterly water testing results are received. If *Legionella* is again found in the building's water distribution system at the next quarterly testing, then the heightened state of clinical vigilance must continue for another 3 months. If *Legionella* are not found in the building's water system, then the state of heightened clinical vigilance may end, and the VA medical facility may return to conducting routine clinical testing.

(2) If a case of LD is diagnosed at the VA medical facility, see paragraph 3.c. of this Appendix for determination of linkage of the case to the health care facility.

c. **Determination of Epidemiological Linkage of LD Cases to the Health Care Facility for Assessment of Remediation Needs.** If diagnostic testing determines that any case of pneumonia is caused by any species of *Legionella*, then determine if the case is epidemiologically linked to the building using the following guidance.

(1) **Presumptive HCA LD.** If the person has spent 10 or more days continuously in a VA medical facility in the 14 days prior to the onset of pneumonia symptoms, then the case is classified as presumptive HCA LD. The remedial actions in paragraph 3.d. of this appendix are required. ***NOTE:*** *"Presumptive HCA LD" was called "definite HCA LD" in previous policy. Classification of an HCA LD case as "presumptive" is a temporal determination based on length of continuous stay at the VA medical facility (at one or more buildings). Therefore, collection of water to determine if* Legionella *are detected is not a component of deciding if remediation is needed. Rather, such water collection prior to remediation is an option to assess the environmental situation (see paragraph 3.c.(2)(a) and paragraph 3.d.(2) of this appendix for more information on such water collection).*

(2) **Possible HCA LD.** If the patient or resident had exposure to a health care facility for a portion of the 14 days prior to onset of illness, regardless of whether that contact occurred during an inpatient stay or outpatient visit/non-clinical contact (e.g., prescription pick up), then the case is classified as possible HCA LD. Possible HCA LD can be the result of only outpatient/non-clinical exposure in the 14 days prior to symptom onset, or only inpatient exposure in the 14 days prior to symptom onset, or both outpatient/non-clinical and inpatient exposure. The VA medical facility must assess possible association of an LD case with the VA medical facility on a case by case basis. Conduct the following actions to determine if remediation of the VA medical facility water system(s) is necessary.

(a) For possible HCA LD resulting from inpatient exposure, collect environmental water samples from the hot and cold water distribution loops in at least the areas where the patient had contact with the building water distribution systems, including samples from ice machines and medical devices/equipment that may have been involved in exposure of the patient to water. Consider collection of swab samples of the outlets where water samples are collected. ***NOTE:*** *CDC recommends collection of one-liter water samples and swab samples for investigation of LD cases. Consider non-potable water sources, such as cooling towers, if epidemiologically indicated. The environmental samples are to be processed for the culture of* Legionella *bacteria to determine if the species responsible for the person's illness is detected in environmental samples.*

(b) For possible HCA LD resulting from only outpatient or non-clinical exposure, consider factors that could indicate increased likelihood that the LD may have been a result of contact with the building such as use of water sources by the person or other cases of HCA LD with exposure to the same building in the past 12 months. The Facility Water Safety Committee must determine the extent of investigation needed, including a

decision on whether water samples will be collected. ***NOTE:*** *Consultation with NIDS is available for guidance.*

(c) If any of the environmental testing results are positive for *L. pneumophila*, or the species of *Legionella* associated with the case (if the case was not caused by *L. pneumophila*), then the remedial actions in paragraph 3.d. of this appendix are required.

(d) If the environmental testing does not detect *L. pneumophila*, or the *Legionella* species associated with the case, then clinical staff are to remain vigilant for the identification of additional cases of LD for at least the next 3 months. Any LD-positive diagnostic result precipitates the actions in paragraph 3.c. of this appendix to determine if the case is linked to the VA medical facility. ***NOTE:*** *Based on local conditions or circumstances, the Facility Water Safety Committee may determine that remediation is to be conducted even if the criteria above are not met. Consultation with HEFP and NIDS is available for guidance.*

(3) If the VA medical facility compares patient and environmental *Legionella* isolates by molecular typing and the isolates are determined to be closely related, then the case is epidemiologically linked to the VA medical facility regardless of the duration of time the patient spent in the VA medical facility or the nature of the visit. The remedial actions in paragraph 3.d. of this appendix are required.

(4) If an HCA LD case is identified (whether presumptive, possible or molecularly linked), then implement heightened awareness for clinical testing as described in paragraph 3.b. of this appendix for a period of at least 3 months.

d. **Remedial Actions.** Linkage of a case of LD to the VA medical facility as described in paragraph 3.c. of this appendix requires the following immediate actions.

(1) The Facility Water Safety Committee must meet and review data on the implementation of the primary engineering controls and any supplemental actions to determine if there were any circumstances (e.g., construction activities, reduced water temperatures, reduced biocide residual levels) that could have resulted in *Legionella* growth and that require corrective action to restore the controls and systems to levels for ongoing suppression of *Legionella* growth. ***NOTE:*** *If the Facility Water Safety Committee discusses any case of LD, patient information must be de-identified prior to sharing the information with the committee.*

(2) Implement remediation, described in Appendix A, paragraph 4, as an immediate remediation of the potable water distribution system(s) in the building. Consider cleaning ice machines, medical devices and equipment as a way to prevent potential further transmission of *Legionella* if such apparatus may be associated with the diagnosed case. In the situation of a presumptive HCA LD case where taking environmental samples may not have been necessary to link the case to the VA medical facility, it may be prudent to collect environmental samples prior to implementing remediation to determine the extent of *Legionella* in the building water distribution system(s); however, remediation is not to be delayed until results are returned and not

to be canceled if results are all negative. Retest the water after remediation is complete to determine if the remediation was successful at reducing *Legionella* to undetectable levels. Detection of *Legionella* in subsequent environmental testing prompts a review of remediation procedures and further remediation and testing to reduce *Legionella* to undetectable levels. ***NOTE:*** *Consultation with HEFP is available for guidance on remediation.*

e. **Case Reporting.** Ensure that LD cases (community-associated and VA-associated) are reported as indicated in the directive (paragraphs 5.g.(8)(a) and 5.g.(8)(b)).

4. COMMUNICATION OF VALIDATION ACTIVITIES AND RESULTS AT THE VA MEDICAL FACILITY

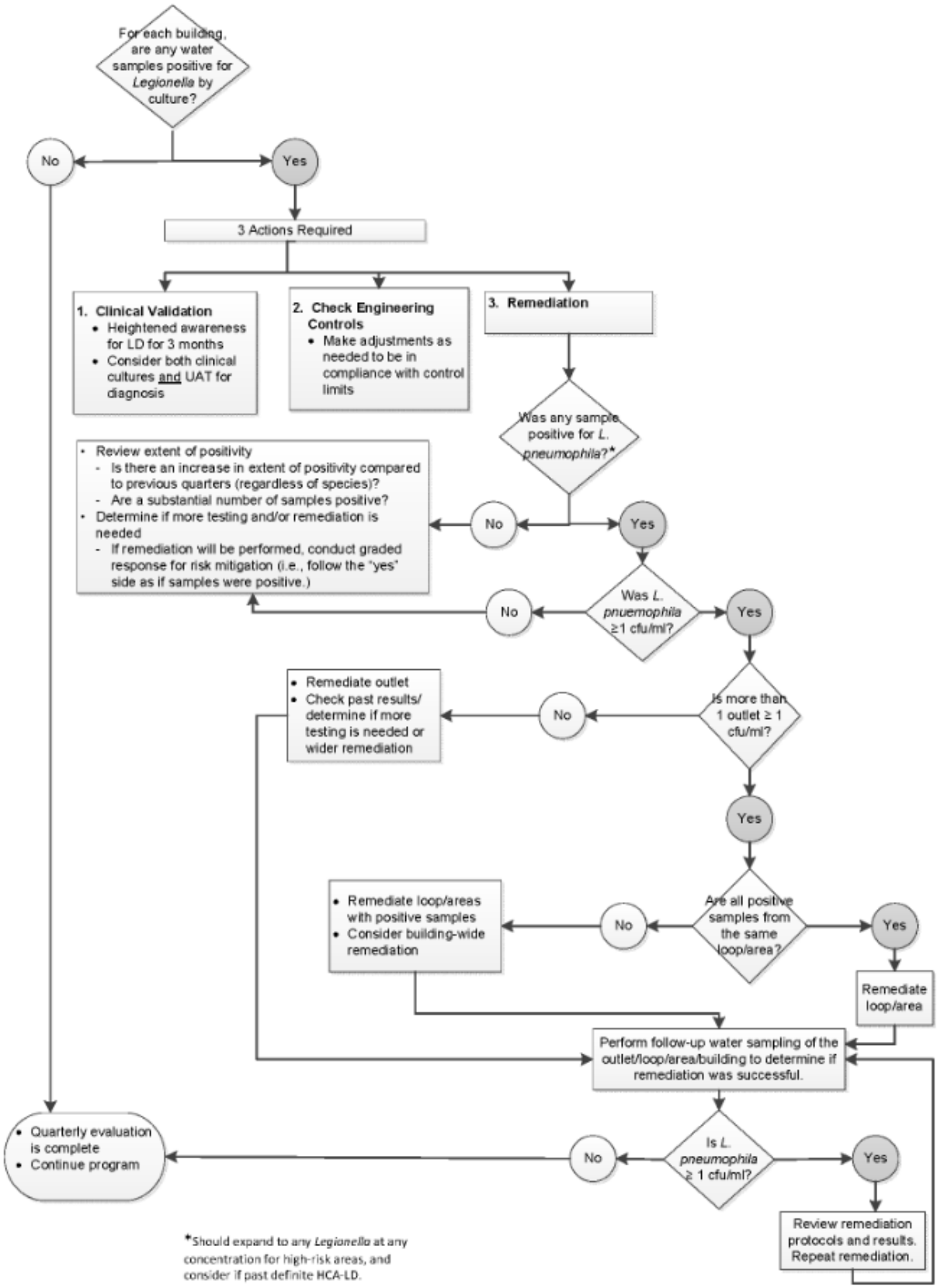
Legionella prevention and control in the health care setting is multidisciplinary. Effective prevention of HCA LD requires timely communication among staff. This is especially important regarding interpretation and follow-up for positive validation results as delineated in this appendix, since positive results in one section triggers required actions in other sections.

a. If the results of the environmental validation are determined to be positive for *Legionella*, the following must be promptly notified of the type of *Legionella* detected and the location(s): VA medical facility Chief of Staff, the Associate Director for Patient Care Services, the Facility Water Safety Committee Chair, Infection Prevention and Control and Facility Chief Engineer or Facility Manager. The Chief of Staff and the Associate Director for Patient Care Services are responsible for ensuring that clinicians involved in direct patient care are notified of the positive environmental results, including the species and serogroup detected (if appropriate), in order to implement heightened awareness for clinical testing for LD as required in paragraph 3.b. of this appendix, and in accordance with the building HCA LD prevention plan.

b. If there is a presumptive or possible HCA LD case at the VA medical facility, Infection Prevention and Control must promptly notify the Chief of Staff, the Associate Director for Patient Care Services and the Facility Water Safety Committee Chair. This notification of the Facility Water Safety Committee Chair will initiate the committee's review of engineering controls and implementation of the emergency remediation process, as appropriate, described above in paragraph 3.c. of this appendix.

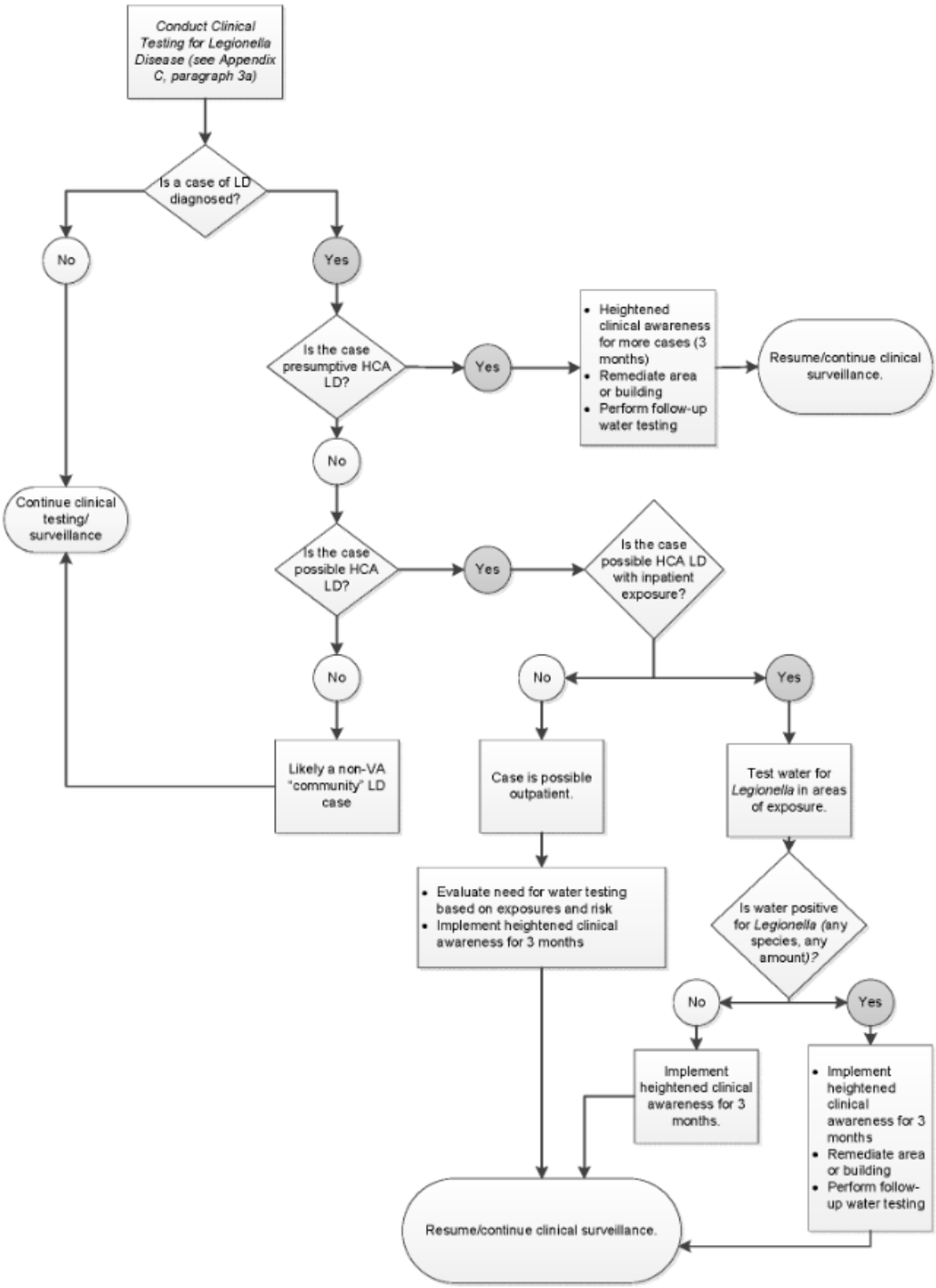
5. SUMMARY FLOW CHART FOR INTERPRETATION OF ROUTINE QUARTERLY ENVIRONMENTAL WATER TESTING CULTURE RESULTS IN THE ABSENCE OF HCA LD

This flow chart summarizes the main concepts in Appendix C regarding Environmental Validation processes. For a summary of Clinical Validation processes, see the flow chart in paragraph 6. For details on these validation processes, see the text in Appendix C.


For each building, are any water samples positive for *Legionella* by culture?
No
Yes
3 Actions Required
1. Clinical Validation
• Heightened awareness for LD for 3 months
• Consider both clinical cultures and UAT for diagnosis
2. Check Engineering Controls
• Make adjustments as needed to be in compliance with control limits
3. Remediation
Was any sample positive for *L. pneumophila*?*
No
Yes
• Review extent of positivity
- Is there an increase in extent of positivity compared to previous quarters (regardless of species)?
- Are a substantial number of samples positive?
• Determine if more testing and/or remediation is needed
- If remediation will be performed, conduct graded response for risk mitigation (i.e., follow the "yes" side as if samples were positive.)
Was *L. pnuemophila* ≥1 cfu/ml?
No
Yes
Is more than 1 outlet ≥ 1 cfu/ml?
No
• Remediate outlet
• Check past results/ determine if more testing is needed or wider remediation
Yes
Are all positive samples from the same loop/area?
No
• Remediate loop/areas with positive samples
• Consider building-wide remediation
Yes
Remediate loop/area
Perform follow-up water sampling of the outlet/loop/area/building to determine if remediation was successful.
Is *L. pneumophila* ≥ 1 cfu/ml?
No
• Quarterly evaluation is complete
• Continue program
Yes
Review remediation protocols and results. Repeat remediation.
*Should expand to any *Legionella* at any concentration for high-risk areas, and consider if past definite HCA-LD.

6. SUMMARY FLOW CHART FOR CLINICAL VALIDATION

This flow chart summarizes the main concepts in Appendix C regarding Clinical Validation processes. For a summary of Environmental Validation processes, see the flow chart in paragraph 5. For details on these validation processes, see the text in Appendix C.



NOTE: *If molecular typing was done and the patient* Legionella *isolate matches an environmental* Legionella *isolate, then follow the actions associated with a presumptive case of HCA LD.*

PREVENTION OF *LEGIONELLA* DISEASE FROM COOLING TOWERS AT DEPARTMENT OF VETERANS AFFAIRS MEDICAL FACILITIES

1. BACKGROUND

Non-potable water is water that is not of drinking quality but may be used for other purposes. Examples of systems that use non-potable water include cooling towers, which present a particular risk for *Legionella* exposure because they can provide an environment for growth of *Legionella* and subsequent transmission via water vapor or droplets emitted from the systems. Cooling towers have been identified as a source for outbreaks of *Legionella* disease (LD), which have included numerous cases identified over a short period of time. Conditions such as humidity, wind velocity and other factors can influence the travel distance of the contaminated aerosols. Since the aerosols generated by cooling towers can travel some distance, some LD cases have been reported to occur several miles away from the source. *Legionella* growth in cooling towers can be controlled through prevention and mitigation methods. These practices are critical to mitigate frequent and extended exposure of large numbers of people to *Legionella*-contaminated aerosols. This appendix delineates requirements for addressing the risk of *Legionella* growth in, or transmission from, cooling tower systems.

2. REQUIREMENT

Each Department of Veterans Affairs (VA) medical facility that owns and operates one or more cooling tower systems must ensure that a Cooling Tower Policy and Cooling Tower Management Plan is developed for the systems and that it remains current at all times.

3. VA MEDICAL FACILITY POLICY AND PLAN FOR MANAGEMENT OF COOLING TOWER SYSTEMS

The Cooling Tower Policy must be reviewed and updated whenever there are additions, significant changes or, at least every 5 years. The Cooling Tower Management Plan must be reviewed, certified and updated annually at a minimum. The Cooling Tower Management Plan must include the following:

a. **Cooling Tower Inventory.** Document the location of every cooling tower system at the VA medical facility. Identify the technical details of the cooling tower(s), including the manufacturer and model, size and date of manufacture.

b. **Systems Risk Analysis.** At a minimum, for each cooling tower on the campus, the Cooling Tower Management Plan must address the following critical risks that can directly or indirectly impact *Legionella* growth or transmission.

(1) **System Design and Operation.**

(a) The design of the system must undergo a documented risk analysis to ensure that the performance criteria are met and that the design addresses the risks discussed below.

(b) Siting and access of a cooling tower/cooling tower system must be reviewed for impact of drift and water vapor discharge relative to Heating, Ventilating and Air Conditioning (HVAC) air intakes, door and window openings, as well as the common path of travel and congregation of patients, staff and visitors. Additionally, the impacts of structures and other equipment on the operation of the equipment and systems must be reviewed.

(c) The sequence of operation must be reviewed to verify that the equipment can be operated as designed and that the operation addresses the risks discussed below. The review must be documented.

(d) There must be a current system schematic with detail on the system interconnection, equipment and instruments complete with a written sequence of operation for the system and the chemical treatment systems.

(2) **Flow Analysis.**

(a) The system must be reviewed for proper circulation in all branches of the non-potable system and in the presence of dead-end piping and stagnant areas.

(b) This review must include an understanding of operation, and address stagnation and low flow as a result of operation of system valves and controls. The review must be documented.

(3) **Biological/organic Material.**

(a) The presence of biofilm, algae and protozoa in a non-potable water system will be accelerated by the presence of required nutrients, such as organic material, and optimal growth conditions, such as warm water. The VA medical facility must establish a plan to minimize these conditions, or the effect of the conditions, and ensure optimal system control.

(b) The exposure of the water in a cooling tower system to direct sunlight also may accelerate biological growth and fouling.

(4) **Poor Water Quality.**

(a) Since the cooling tower inherently removes contaminants from the air that passes through it, organic and inorganic material near the tower must be controlled to mitigate contamination of the tower should these substances become airborne. An evaluation of these issues must be conducted to develop a plan to minimize their impact.

(b) The Municipal water supply quality must be verified in order to ensure the chemical treatment regime provides the desired cooling tower water quality, and optimize blowdown, makeup and treatment options.

(5) **Cooling Tower Equipment.** Refer to VHA Engineering Standard ES-2019-001 for information and requirements related to the equipment and its maintenance and operations located at:http://vaww.hefp.va.gov/resources/water-safety-management-legionella-vavha-policies-guidance-supplements. ***NOTE:*** *This is an internal VA website that is not available to the public.*

c. **System Operational Requirements and Procedures.** There must be a current written operating plan for each system. The plan must include:

(1) System schematic with all equipment and instrumentation uniquely labeled (tag number) including chemical treatment. All equipment, valves and instruments must be physically labeled to match the schematic.

(2) Detailed sequence of operation for all modes of operation to include chemical treatment system. Sequence of operation must reference and be correlated with the schematic. Requirements for the sequence of operation, monitoring, operation and maintenance of the cooling tower and systems is defined in VHA Engineering Standard ES-2019-001.

(3) Process to address any deficiencies or concerns raised in a report from any person related to the control measures being inadequate or requiring improvement.

d. **System Maintenance Requirements, Frequencies and Procedures.** There must be a current written maintenance plan for each piece of equipment and system that complies with the requirements of this directive, VHA engineering standards and the manufacturer's recommendations and industry standards. The details of the requirements for the plan, inspections and reporting intervals are defined in VHA Engineering Standard ES-2019-001.

e. **Procedures/Plans for Emergency Action Related to Biological Exceedances.** There must be a current written Emergency Action Plan for each system that complies with the requirements of this directive, VHA engineering standards, the manufacturer's recommendations and industry standards. The plan must include:

(1) Procedures to address positive biological findings during testing.

(2) Standard operating procedures for remediation of equipment in addition to procedure for operating the system equipment during remediation process.

(3) Process to confirm if remediation was successful and if not, what further action is to be taken.

(4) Required personal protective equipment (PPE) during remediation.

(5) Required material, equipment and supplies to properly remediate.

(6) Details on what the intended outcome is, as well as a method of documentation and evaluation.

(7) Process to address any deficiencies or concerns raised in a report from any person related to the remediation process.

f. **Water Chemistry and Biological Testing Requirements, Frequencies and Procedures.** There must be a current written Testing Plan for each system. The plan must include the following at a minimum:

(1) A list of all systems with testing frequency, thresholds and requirements. All systems must be tested as defined in this directive or per the manufacturer's requirement, whichever is more stringent, including frequency.

(2) Written standard testing procedures for each system, including specific procedures for:

(a) Process to obtain sample, standard sample size and chain of custody process.

(b) Required PPE.

(c) Required material, tools and supplies to complete the work properly.

(3) **Water Chemistry Testing Requirements.**

(a) Water chemistry must be continuously monitored for biocide, corrosion control, pH, conductivity and turbidity. Water temperature also must be continuously monitored.

(b) Data on the water quality must be collected on the water chemistry hourly and upon alarms.

(c) Biocide and corrosion control additions must be automated and based on monitoring input.

(d) Water chemistry must be manually tested each month to confirm and recalibrate the accuracy of the continuous monitoring systems.

(4) Written biological testing procedures and frequencies using the requirements listed in paragraph 4 of this appendix.

(5) Process to address any deficiencies or concerns raised in a report from any person related to the testing process.

g. **Data Evaluation and Record Keeping Requirements and Procedures.** There must be current written records and an Evaluation Plan for each system. The plan must include:

(1) A process that defines the data to be collected and the form it must be in. At a minimum, the following must be addressed for each cooling tower/system:

(a) Maintenance and inspection data on the cooling tower and systems;

(b) Water chemistry testing and monitoring data and deviations;

(c) Chemical treatment data, changes to rates of injection and data on why rates were modified;

(d) Environmental testing data and water chemistry and temperature of tests; and

(e) Remediation and supplemental action data.

(2) The method used to evaluate the data and any actions that need to be taken relative to any deviation or trends associated with the data;

(3) Identifying responsible persons for each process; and

(4) A method for filing, data retention and data retrieval.

4. BIOLOGICAL TESTING PROTOCOL AND INTERPRETATION OF RESULTS

This section provides overarching requirements for testing cooling towers for bacteria and describes actions to be taken.

a. ***Legionella* Validation Testing.** Sampling of each cooling tower for *Legionella* by culture methodology must be performed within 7 days of startup and every 90 days during periods when the cooling tower is operational or operational-ready (i.e., cleaned, disinfected, full of water and ready for operation). For routine water testing, collection of swab samples is not required, although a VA medical facility may choose to collect swab samples in addition to water samples. Swab samples alone do not meet the requirement of this directive.

(1) **Sample Number and Locations.** The number of water samples is dependent on the size and configuration of the cooling tower. At a minimum, samples must be collected from each basin/sump, and the supply to and return from the chiller(s). If the chillers are on a common header, only one sample is required. ***NOTE:*** *Depending on the time of the year and VA medical facility location, a VA medical facility may have some cooling towers that are operational and some that are not. These testing requirements only apply to those cooling towers that are operational or operational-ready.*

(2) **Additional Sample Information.** At the time that cooling tower water samples are collected for *Legionella* detection, also collect the following information for each sample: pH, biocide level and temperature.

(3) **Laboratory Requirements.** Once collected, samples are to be processed for *Legionella* detection by a testing laboratory with proficiency in microbial testing of cooling tower water. ***NOTE:*** *Refer to Appendix C, paragraph 2.b. for requirements for choosing a laboratory for* Legionella *testing.*

(4) **Testing Modality.** All cooling tower water samples must be analyzed using a *Legionella* culture method. Use of additional *Legionella* detection methods (e.g., PCR) is a local decision; however, the use of PCR to screen for *Legionella*-negative samples ("PCR negative screen") to then decide which samples must then be cultured is not permitted.

(5) **Interpretation of *Legionella* Culture Results from Water Testing and Mitigation Actions.** Below are the minimum action levels and requirements in response to cooling tower *Legionella* culture results.

(a) Sample is <10 colony forming units per milliliter (CFU/ml) - No action required, Maintain Cooling Tower Management Plan

(b) Sample is ≥10 CFU/ml to <1,000 CFU/ml - Review system operations including chemical treatment system. Perform immediate Remediation for cooling towers (see note below, paragraph 4.a.(5)(d)1.). Retest the cooling tower 3-7 days after completion of Remediation. If retest is ≥10 CFU/ml and <1000 CFU/ml, repeat Remediation for cooling tower (at increased concentrations) and retest at same interval until <10 CFU/ml is attained. If retest is ≥1,000 CFU/ml see paragraph 4.a.(5)(c). Review Cooling Tower Management Plan and update as necessary (e.g., using information from assessment of system operations, *Legionella* positivity results and response efforts).

(c) Sample is ≥1,000 CFU/ml - Review system operations including chemical treatment system. Perform immediate Disinfection for cooling tower (see note below, paragraph 4.a.(5)(d)2.). Retest the cooling tower 3-7 days after Disinfection. If retest is ≥10 CFU/ml and <1000 CFU/ml, conduct Remediation for cooling tower and retest at same interval until <10 CFU/ml is attained. If retest is ≥1000 CFU/ml: Immediately perform Disinfection for cooling tower at an increased concentration/duration AND retest and repeat actions until <10 CFU/ml is attained. Review Cooling Tower Management Plan and update as necessary (e.g., using information from assessment of system operations, *Legionella* positivity results and response efforts).

(d) Notes.

1. Remediation for cooling towers. Treat the cooling tower water system with either a different biocide or a similar biocide at an increased concentration than what is currently used. Treatment must be maintained for a minimum of 2 hours, or longer if required to ensure the chemical is circulated throughout the system fully.

2. Disinfection for cooling towers. Dose cooling tower water system with a minimum of 10 mg/L of free residual halogen and dispersant for at least eight hours. Then the system is drained and flushed with clean water and the wetted surfaces are cleaned (cooling tower sump, fill, drift eliminators, etc.). Following this, the system is refilled, dosed to 1 to 5 mg/L of free residual halogen and circulated for 30 minutes, then drained. Finally, the system is refilled, routine treatment is re-established, and retesting is done for verification of treatment.

3. Please refer to the following pH ranges for the selected halogen. For chlorine treatment, the pH should be 7.0 – 7.6; and for bromine treatment, the pH should be 7.0 – 8.7. For higher pH values treatment times may need to be extended.

4. Stabilized halogen products should not be used for remediation or disinfection.

(6) **Documenting Testing Results.** Documentation is required for environmental *Legionella* testing (e.g., date, location and results), any assessments of positive results, any remedial action taken and efficacy of remedial actions. A report of these items is to be submitted to the Facility Water Safety Committee, Facility Safety and Health Leadership Committee and Infection Control Committee.

(7) **Reporting Environmental Testing Results.** VA medical facilities are required to report environmental testing results, taken in accordance with *Legionella* testing requirements in this directive, to the VHA Water Safety Management Tool (WSMT) database or equivalent. ***NOTE:*** *This requirement pertains to reporting of samples taken specifically for* Legionella *testing, including related readings such as pH, biocide level and water temperature. It does not pertain to reporting of routine or continual engineering control monitoring; these results should be recorded locally to monitor implementation of controls.*

(a) The required content, frequency and timeframe for reporting results to the WSMT must be in accordance with the database User Manual. ***NOTE:*** *The current WSMT User Manual can be found at the VHA Water Safety Management &* Legionella *Resources intranet site at: http://vaww.hefp.va.gov/healthcare-engineering/water-safety-management-legionella. This is an internal VA website that is not available to the public.*

(b) Reporting of environmental *Legionella* testing results from cooling towers is required for samples taken for any component of this directive, such as routine testing, post-remediation testing or investigation of a LD case or cases. ***NOTE:*** *VA medical facilities are required to report and verify the number of cooling towers that are operational and operational ready in the WSMT or equivalent on a quarterly basis in accordance with the User Manual*.

b. **Total Aerobic Bacteria.** Total aerobic bacteria testing can provide information on whether engineering controls are preventing bacterial growth. Total aerobic bacteria testing is to be performed at system start up and every two weeks while the cooling tower is in use. Information regarding total aerobic bacteria testing requirements and interpretation of results can be found in VHA Engineering Standard ES-2019-001. ***NOTE:*** *While total aerobic bacteria testing (of which heterotrophic plate counts, or HPC, is one example) can provide information about general water quality in the cooling towers, there is no reliable correlation between total aerobic bacteria and* Legionella *values. The HPC testing requirement is included in this document as a reminder and is additional to the* Legionella *testing described here.*

OUTDOOR NON-POTABLE, AEROSOL-GENERATING WATER SYSTEMS OTHER THAN COOLING TOWERS ON VHA MEDICAL CAMPUSES

1. BACKGROUND

Outdoor non-potable, aerosol-generating water systems other than cooling towers include, for example, irrigation systems, pond aeration systems and misters (refer to paragraph 5.h.(5) of the body of this directive for information on prohibition of decorative fountains). These types of devices can present a risk for *Legionella* exposure because they can provide an environment for growth of *Legionella* and subsequent transmission via water vapor/droplets. While outbreaks of *Legionella* disease (LD) have not been found to be linked to these sources, it is critical that potential risks be evaluated, and systems be well-maintained. Conditions such as humidity, wind velocity and other factors can influence the travel distance of the contaminated aerosols. This appendix delineates requirements for addressing the risk of *Legionella* growth in, or the transmission from, outdoor non-potable, aerosol-generating water systems. ***NOTE:*** *Requirements for* Legionella *risk assessments and mitigation related to cooling towers at Department of Veterans Affairs (VA) medical facilities are described in Appendix D.*

2. RISK ASSESSMENT

The following actions are required.

a. Document the presence of any outdoor non-potable, aerosol-generating water systems (other than cooling towers). This list must be reviewed and updated annually and subsequent to any construction or demolition activities that add or remove these systems.

b. For each system identified in paragraph 2.a. of this appendix, the VA medical facility must document associated risks pertaining to *Legionella* growth and transmission. Considerations for risk include:

(1) The degree to which the system generates aerosols that pose an inhalation risk. For example, a sprinkler-type irrigation system produces more aerosolized water droplets that travel further distances than does a drip irrigation system;

(2) Whether or not the system is treated with biocides;

(3) How often the system is operated, indicating the propensity for water stagnation;

(4) The proximity of Heating Ventilating and Air Conditioning (HVAC) intakes, patients and staff to activity; and

(5) The time(s) of day that the system is operated. ***NOTE:*** *Other than the requirements for* Legionella *testing of cooling towers (see Appendix D), the testing of other outdoor non-potable water systems for* Legionella *or other bacteria is not required*

by this directive. If a VA medical facility chooses to do such testing, either routinely or sporadically, then the results of such testing must be included in the risk assessment.

3. MAINTENANCE AND OPERATIONS

a. Maintaining water quality at approximately the biocide levels received from the municipality are critical to mitigate potential *Legionella* impacts. Flushing of systems and draining of systems when not in use must be part of this process.

b. There must be a plan for the operation, maintenance and startup/shutdown of these systems.

c. Siting of the systems is critical to mitigate potential impacts from aerosolization. Planning must include review of HVAC intakes, areas of pedestrian traffic (e.g., sidewalks) and congregation areas (e.g., gazebos). Properly locating systems and timing operations (i.e., other than business hours) can minimize potential impacts.