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Risk Assessment for Prevention of Healthcare-Associated *Legionella* Disease

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Veterans Health Administration Water Safety Oversight Committee

The Veterans Health Administration (VHA) Water Safety Oversight Committee (WSOC) was chartered by the Under Secretary for Health on May 7, 2014, to serve as an expert advisory group on financial, legislative, and scientific matters related to the prevention of waterborne disease to the Administration. Development, oversight, and implementation of policy and guidance is integral to the Committee's charge.

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**Risk Assessment for Prevention of Healthcare-Associated
Legionnaires' Disease**

PURPOSE and SCOPE: This document was produced by the **VHA Legionella Risk Assessment Work Group**, composed of VHA Central Office and facility representatives, and includes content proposed by facility and VHA Veterans Integrated Service Network (VISN) staff at a national educational *Legionella* workshop. This document was reviewed by the VHA Water Safety Oversight Committee for approval and national distribution. Members of the Committee include subject matter experts at VA, VHA, VISN and facility levels.

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Purpose and Scope

The purpose of this document is to provide supplementary information to VHA Directive 1061 for implementing the risk assessment component of a building's Plan for prevention of healthcare-associated (HCA) *Legionella* disease (LD) (see paragraph 1.b. in Appendix A of the Directive). A "risk assessment" is the process of identifying hazards (i.e. risk factors) that may result in an undesirable outcome (in this case, HCA LD). Development of a risk assessment for HCA LD will assist VHA healthcare facilities in understanding and controlling risks associated with *Legionella* based on local conditions, as well as contribute to prioritization of actions. **NOTE:** *The definitions listed in paragraph 6 of VHA Directive 1061 pertain to this guidance document.*

Since there are a number of factors related to *Legionella* growth in buildings and disease in people, risk assessments can be complex. Each building at a facility may have its own considerations. This document provides overarching categories and concepts related to risk. While it cannot provide an exhaustive list of every issue at every building, it is intended to contain sufficient detail and guidance to assist facilities in developing their own assessments. Accordingly, this document provides some examples and templates for conducting risk assessments that facilities may choose to use or adapt for their own purposes.

Background: VHA Policy for *Legionella* Risk Assessments

Legionella is a Gram-negative bacterium that can cause diseases, primarily respiratory, collectively referred to as legionellosis. The bacteria, found naturally in water worldwide, have been associated with disease from building water distribution systems and other water sources in the built environment. Non-natural water sources, especially hot water systems, are known to be conducive to *Legionella* growth and, subsequently, a source of transmission of the bacteria to the people. *Legionella* generally cannot be eliminated from building water systems but growth can be suppressed through prevention and mitigation efforts.

Healthcare facilities are among the types of buildings that have been associated with outbreaks of disease. Accordingly, VHA has had policy in place since 2008 to address *Legionella* risk assessment and disease prevention at VA medical facilities. This risk assessment and prevention focus is continued in the updated VHA *Legionella* prevention policy, VHA Directive 1061 (Prevention of Healthcare-Associated *Legionella* Disease and Scald Injury from Potable Water Distribution Systems), published August 13, 2014.

Per VHA Directive 1061, a written HCA LD prevention plan ("Plan") must be developed and reviewed, at least annually, for each building under the purview of the policy (i.e. VHA-owned buildings in which patients, residents, or visitors stay overnight). The components of the Plan include schematic and process flow diagrams, a building risk assessment for HCA LD, implementation and monitoring of engineering controls, validation that the engineering controls are effectively preventing *Legionella* growth, and scald prevention. The Plan, of which the risk assessment is an integral component, drives the activities and actions at the building to prevent HCA LD. Furthermore, the risk assessment can be used to determine a long-term plan to address building infrastructure improvements in a systematic way base on priority to allow a cohesive approach to the overall issue.

KEY POINT: The Risk Assessment is a formal, written, component of the HCA LD prevention plan and, per VHA Directive 1061, must be updated at least annually.

Risk Factors

Building – Physical Water Distribution System Risk Factors

Understanding the building's water distribution system(s) and associated equipment (e.g., tanks, heat exchangers, temperature-reducing devices, outlets) will help determine if there is a risk of conditions conducive to *Legionella* growth and, therefore, risk of HCA LD. Consider the following when conducting the risk assessment:

- Presence of data and information that can assist with understanding building risk factors and are key components in developing a risk assessment and prioritizing actions:
 - Availability of accurate schematic drawings of the site distribution and water distribution systems.
 - Availability of automated water temperature and water chemistry monitoring data and trends.
- Ability to generate hot water at a temperature of at least 130 degrees Fahrenheit (°F), or 140°F if hot water storage tanks are used.
- Ability to maintain water in the hot water distribution system at a minimum of 124°F (prior to end-point mixing valves).
- Ability to maintain biocide levels throughout the hot and cold water distribution systems at locally determined minimums.
 - If a supplementary systemic disinfection system is being used to implement biocide in the water distribution system(s), assess whether the system is operating as expected for *Legionella* control.
- Ability to prevent water from stagnating in the system. Stagnant water can lead to ideal *Legionella* growth conditions through biocide degradation, reduction of hot water temperature, and increase in cold water temperature in the distribution system. Flowing water to maintain biocide and/or water temperature is a key component to preventing *Legionella* growth. Therefore, the following criteria related to stagnant water should be considered in the risk assessment:
 - Understanding of piping system and prioritization and removal of vulnerable areas such as:
 - Presence of dead end piping (pipe ends in cap, blind flange, valve with plug, or closed valve in a pipe line). Mitigation occurs through removal since a dead end cannot be flushed to mitigate. Removal of dead ends should be prioritized by risk.
 - Presence of unused/underutilized water branch lines/fixtures (fixture run-out). May be mitigated through flushing or re-piping.
 - Level to which a flushing program assures fixtures throughout the building are utilized at least twice weekly (through water flushing or normal use)
- Ability to maintain cold water temperatures below the locally determined maximum temperature.
- Mixing valve placement for regulation of water temperatures at the outlet in order to prevent scalding.
 - The further the valve from the outlet, the longer the length of pipe where water temperature is conducive to *Legionella* growth and the greater the risk. **NOTE:** *Even mixing valves placed close to the outlet result in a segment of piping, albeit shorter, where Legionella can grow. This is the compromise for mitigating both scald injury and Legionella risk.*

- Habitual detection of *Legionella* (especially *L. pneumophila*) in the building water distribution system during routine water testing (see the “Trending Risk Factor Data” section for more information).
- Presence of construction and maintenance activities that can affect the building water distribution system and promote conditions conducive to *Legionella* growth or transmission (e.g., disruption in water service, temporary capping of pipes, reduced or no water flow, water pressure changes). **NOTE:** *Before construction or maintenance work is initiated, either by VA staff or contractors, an Infection Control Risk Assessment (ICRA) is required to determine if/how the activity may affect the water distribution system (see VHA Directive 1061, paragraph 4.g.(5)). The ICRA findings, and implementation of related actions (e.g., flushing/disinfection post-activity), should be factored into the risk assessment for HCA LD.*
- Presence of sources of nutrients (e.g., biofilm, rust, scale, organic matters, etc) that allow the bacteria to thrive.

There may be other areas of consideration from a building perspective beyond a building’s potable water distribution system when assessing risk for LD. While the following are outside the scope of VHA Directive 1061, they have been included in this document because of their association with LD cases or *Legionella* growth.

- Cooling towers and evaporative condensers
- Outdoor decorative water fountains

Building – Equipment and Medical Devices

There may be equipment or devices that are not associated with the physical infrastructure of the building, but their presence in the building may be a potential source of transmission of *Legionella* bacteria. Consider the presence of and maintenance protocols/records for the following equipment or medical devices when conducting the risk assessment.

- Ice machines, especially in areas used for patients who are critically ill or post-surgery since ice chips are often provided when drinking fluids is not possible
- Bathing equipment associated with generation of aerosols (e.g., whirlpool tubs)
- Nebulizers, continuous positive airway pressure (CPAP) devices, ventilators or other respiratory therapy equipment
- Emergency showers
- Dental unit water lines may have *Legionella spp.* present; however, there is very little documented evidence of their implication as the source of *Legionella* infection. Nonetheless, there can be cause for concern due to the growing number of vulnerable individuals. Facilities may want to determine whether standard dental unit water line maintenance, cleaning and monitoring is being conducted when assessing *Legionella* risk.

Building Clinical Risk Factors

There may be additional risk factors that do not pertain to the physical infrastructure of the building, but are clinical considerations associated with the building for increased risk of LD. Consider the following when conducting the risk assessment:

- History of epidemiologically-linked HCA LD case(s) to the building.
 - When a facility has been associated with a case of HCA LD, then it is known that a strain of *Legionella* is present that can cause disease.
 - Evidence indicates that *Legionella* can survive in building water distribution systems for decades, even when a rigorous engineering control program is in place. Therefore, even if the HCA LD case occurred years earlier, the fact that it occurred must be factored into the building's LD risk assessment.

NOTE: *It is understood that improvements may have been made since the case occurred that has reduced Legionella in the water system to undetectable levels, and the length of time since the case may be factored into the assessment. However, the prior case still indicates the importance that those control measures are effective at inhibiting Legionella growth.*

- Community Living Centers and other residential program buildings that provide long-term residence (i.e., where the population is often exposed to building water on a frequent and long-term basis).

Population Risk Factors

In general, individuals at risk for LD include those who are greater than 50 years of age, have chronic lung disease, and/or a history of smoking. Healthcare facilities are considered to be at higher risk for association with LD than other types of buildings since many occupants can have risk factors. Therefore, stratifying healthcare facilities based on population risk may be challenging and the focus for prevention is on mitigating building water distribution system risk factors to improve safety for all occupants. Nonetheless, the presence of units housing certain patients at higher risk for LD should be factored into the building risk assessment:

- The facility is a VHA-designated transplant center for hematopoietic stem cell or solid organ transplantation.
- Hematology-oncology units where chemotherapy is administered, or other such units where the preponderance of patients have underlying immune suppression.

Other Risk Factors

There are *Legionella* risk factors in addition to the characteristics of the building and the occupants for consideration in building risk assessments:

- **Location of the building in the U.S.** There are recognized geographic areas that have a higher incidence of LD than in other parts of the country. This information can be found at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6032a3.htm>.
- **Incoming water quality.** For facilities that use municipal water, the residual biocide level may be low in the water delivered depending on factors such as the type of biocide used by the local water treatment plant and the distance of the facility from the plant. In addition to the physical properties, water chemistry and contaminant types and levels can affect the efficacy of biocides. In some cases, *Legionella* may be present in the water delivered to the facility. **NOTE:** *The buildings in some healthcare systems are spread out over extensive campuses, and the incoming residual biocide level for different buildings on the campus may vary. Therefore, this factor needs to be assessed for each building's risk assessment.*
- **Incoming water temperature.** In some parts of the country, the temperature of incoming water may be above the recommended 68°F for cold water to suppress

Legionella growth. While temperatures slightly above this level may not result in extensive proliferation of *Legionella* and would not be a critical issue, some states, especially in the southern part of the U.S., can experience incoming water temperatures that are much warmer which may contribute to *Legionella* growth in the cold water distribution system (especially if residual biocide in the building is low).

Trending Risk Factor Data

VHA Directive 1061 and related memoranda require extensive collection of data pertaining to *Legionella* risk, such as:

- Building water distribution system physical parameters (e.g., water temperatures and biocide residual levels);
- Testing the potable water for *Legionella* on at least a quarterly basis;
- Testing of patients with pneumonia for LD as clinically appropriate, and recording testing types and results; and
- Testing of incoming water quality (e.g. water temperatures, biocide residual levels, pH, and dissolved solids).

In addition to reviewing these data as they are collected for any necessary immediate actions, comparing data over time can help identify consistent results or trends that may point to continued issues and/or prioritization of areas in need of modification or revision to mitigate issues. For example, a trend analysis of water temperatures and/or biocide levels can help to understand the water distribution system in order to determine adequacy of *Legionella* controls and what changes may need to be made to improve performance. Similarly, trending of environmental *Legionella* results can be used to determine if *Legionella* bacteria are being found habitually in certain areas of the water distribution. Trend data can be particularly useful for the Facility Water Safety Committee during decision making processes and for assessing building risks and associated improvements.

KEY POINT: Data collection, analysis and trending form the foundation of the facility risk assessment and prioritization of actions in the long term.

Mechanisms for Assessing Risk

A HCA LD risk assessment must be completed, at least annually, for each building subject to VHA Directive 1061. The Directive is not prescriptive on how to do the risk assessment so as to allow for local decision-making. Furthermore, the facility may choose how in-depth the risk assessment will be, as long as the process provides reasonable assessment of HCA LD risk to inform decisions. There are different mechanisms that may be used in order to conduct the risk assessment. Listed below are **examples** of various risk assessment approaches. Facilities may choose to use these mechanisms, separately, together, or adapted, to conduct each building's HCA LD risk assessment.

NOTE: While the requirement is to conduct the Legionella Risk Assessment annually, facilities may find they need to do more frequent updates as data/information becomes available (e.g. if a case of HCA LD occurs).

Facility Water Safety Committee Meeting

One way to assess building risk is for the Facility Water Safety Committee to meet and to review the risk factors previously defined and the risk assessment from the previous year. During the meeting, the Committee can review data from at least the previous year (e.g., trend analysis of water testing results, a review of whether there were HCA LD cases) and also assess whether there are any new factors that may change the risk from the previous year. This information can be documented in the Committee's meeting minutes.

Development of a Checklist

A second mechanism to assess risk is for the Facility Water Safety Committee (or subset of members) to develop a checklist consisting of items previously defined. The Committee can add and/or modify to the list depending on the type of building and local factors. This checklist may then be used to assess risk for each building at the VA medical facility that falls under the purview of VHA Directive 1061. The Committee should then meet and the checklist can be used to guide discussion.

Risk Analysis and Management Chart

Another way to assess risk is to conduct an analysis of each building using a process similar to the Hazard Vulnerability Analysis (HVA) that is required by the Comprehensive Emergency Management Program. This would involve identification of risk based on several factors (e.g., previous HCA LD cases, implementation of engineering controls). This process requires involvement by the Facility Water Safety Committee (or subset of members) to complete the assessment on an annual basis to identify risks, assess the probability and impact for each item identified, and delineate mitigation strategies. An advantage of this mechanism is that it includes both risk assessment and management decisions, and may be helpful in tracking actions and progress to mitigate risk. A sample template can be found in Appendix A.

NOTE: *Every building and risk factor is unique; therefore, a "standardized" approach for assigning probability and impact is not within the purview of this document.*

Utilizing the Results of the Risk Assessment

The key goal of the HCA LD Risk Assessment is to identify hazards so that they may be assessed and managed to reduce the likelihood that a case of HCA LD will occur. This section describes uses for the annual Risk Assessment to fulfill this function.

Facilitate Communications

The Risk Assessment, and the process of developing it, may facilitate HCA LD prevention efforts at the facility by formalizing communications. This can lead to:

- A better understanding by various stakeholders at the facility of the *Legionella* risk(s) associated with each building.
- Facilitation of HCA LD risk discussions by the Facility Water Safety Committee during committee meetings and when addressing HCA LD prevention efforts.

- A mechanism for documenting *Legionella* risks, which may be referred to for future risk assessments and can be helpful for informing new members to the Facility Water Safety Committee or other stakeholders.

Risk Management Implementation

The Risk Assessment process can be particularly helpful for addressing a complex issue such as HCA LD prevention since there may be numerous hazards identified.

- Categorizing risks – Some risks are inherent to the system (e.g., past cases of HCA LD, geographic location in the U.S., incoming water quality) and inform the overall “state of importance” for addressing *Legionella* prevention. Other risks are “actionable” (e.g. low water flow) and can be addressed to reduce HCA LD risk.
- Prioritization of actions and development of a long term plan – This is one of the most useful aspect of conducting a Risk Assessment for HCA LD prevention. Given that *Legionella* prevention is complex, there may be numerous risks identified that are actionable. It is often not feasible (or even necessary) to address all such risks at once, and the risk assessment can be used to facilitate the prioritization of risks for implementation of actions. Facilities need to assess these risks using their understanding of local conditions to determine mitigation priorities.
- It is likely that the results of well-executed risk assessment will lead to eventual repairs or updates to a facility’s potable water distribution system. Therefore, facility engineering staff should prioritize system modifications in coordination with the priorities set by this risk assessment. Develop a long term plan to prioritize facility infrastructure modifications or improvements to mitigate risks in the long term.
- Track implementation of risk mitigation efforts and adjust the plan if necessary based on analysis of data and improvements executed.
- Track responsibilities for actions.
- Track effectiveness of mitigation actions.

Appendix A

Sample *Legionella* Risk Assessments

This Appendix provides a few risk assessments samples as information to guide staff when conducting a *Legionella* risk assessment for each building. Staff may find it useful to use one or several of the risk assessments provided or develop their own. Sample 1 is an example of a checklist and Sample 2 includes examples of risk assessment charts that include columns regarding prioritization and progress.

*****These samples are provided as ideas for development of facility-specific risk assessments. As such, they do not contain complete lists of risks. Furthermore, the information in the charts for Sample 2 is notional and does not necessarily represent how facilities should rate or address these example risks*****

Sample 1: *Legionella* Risk Assessment Checklist

This sample uses a checklist format as triggers for assessing presence or absence of *Legionella* risk factors. This checklist is an example and not necessarily complete. **Note:** *The factors listed may not be the actual risk, but a component that may have risk associated with them if not properly addressed/maintained.*

Checklist for Assessment of HCA LD Risk

1. Building – Physical Water Distribution System
 - Accurate schematics in place
 - Monitoring equipment in place and actively collecting data
 - Hot and cold water temperatures, circulating
 - Biocide levels
 - Water stagnation
 - Dead legs
 - Mixing valves
 - Cooling tower(s)
 - *[Add other factors to the list as locally appropriate]*
2. Building – Equipment and Medical Devices
 - Ice machines
 - Respiratory therapy equipment
 - Dental unit water lines
 - *[Add other factors to the list as locally appropriate]*
3. Building – Clinical
 - Presence of community Living Center and/or other residential programs
 - Definite HCA LD case(s)
 - *[Add other factors to the list as locally appropriate]*
4. Population
 - Transplant center
 - Hematology-oncology unit
 - *[Add other factors to the list as locally appropriate]*
5. Other
 - Building location
 - Incoming water temperature
 - *[Add other factors to the list as locally appropriate]*

Sample 2: Legionella Risk Assessment Chart – Example 1

[The information in these charts is notional and does not necessarily represent how facilities should rate or address these example risks]

Risk Description	Trigger(s)	Likelihood/Probability*	Impact*	Response Strategy ⁺	Response Strategy Actions	Responsibility for Actions
Physical Water Distribution System Risk Factors						
Hot water temperatures are <u>not</u> maintained	Hot water temperature falls below 124°F when circulating	P	VH	Mitigate	1) Increase water temperature at the heat exchangers 2) Install recirculating pumps on the loops	Chief, Engineering
Dead legs are present in the water system	1) Building plans identify dead legs present 2) Circulating water temps are outside thresholds 3) Oxidant residuals are not maintained	L	L	Watch/ Mitigate	1) Prioritize and Remove dead leg piping based on anticipated ability to maintain appropriate water temperatures and/or oxidant residual	Chief, Engineering
Equipment and Medical Devices Risk Factors						
Ice machines are present and used for patients/residents	<i>Legionella</i> positive water samples from ice machines	P	P	Mitigate	1) Test ice machines quarterly for <i>Legionella</i> 2) Ensure carbon filters are replaced according to manufacturer specs 3) Ensure maintenance is performed to specs	Chief, Engineering
Clinical Risk Factors						
HCA LD Case(s)	Identification of HCA LD case(s) in previous 3 months	P	VH	Accept	1) Ensure healthcare providers test HCA pneumonia patients for LD 2) Review engineering controls for prevention of <i>Legionella</i> growth 3) Take appropriate action to positive <i>Legionella</i> water samples	Infection Diseases and Infection Prevention & Control

*VL = Very Low; L = Low; P = Probable; H = High; VH = Very High

⁺Mitigate, Accept, Watch

Sample 2: *Legionella* Risk Assessment Chart – Example 2

[The information in these charts is notional and does not necessarily represent how facilities should rate or address these example risks]

Risk Factors Category	Risk Description	Trigger(s)	Likelihood / Probability	Impact	Response Strategy	Action Plan	Risk Owner	Date Opened	Date Closed	Status Update
Physical Water Distribution System	Hot water temperatures are <u>not</u> maintained	Hot water temperature falls below 124°F when circulating	P = Probable	VH = Very High	Mitigate	1) Increase water temperature at the heat exchangers 2) Install recirculating pumps on the loops	Chief, Engineering			
Physical Water Distribution System	Dead legs are present in the water system	1) Circulating water temps are outside thresholds 2) Oxidant residuals are not maintained 3) Building plans identify dead legs present	L = Low	L = Low	Resolve	Remove dead leg piping when identified	Chief, Engineering	3/4/2015		In-progress
Equipment and Medical Devices	Ice machines are present and used for patients/residents	1) <i>Legionella</i> positive water samples from ice machines 2) Molecular linkage from clinical and environmental culture	P = Probable	VH = Very High	Mitigate	1) Test ice machines quarterly for <i>Legionella</i> 2) Ensure carbon filters are replaced according to manufacturer specs 3) Ensure maintenance is performed to specs	Chief, Engineering			

Risk Factors Category	Risk Description	Trigger(s)	Likelihood / Probability	Impact	Response Strategy	Action Plan	Risk Owner	Date Opened	Date Closed	Status Update
Clinical	Definite HCA LD Case(s)	Definite HCA LD case(s) identified. NOTE: Last Definite HCA LD case occurred 8 years ago	L = Low	H = High	Accept	Ensure that this past case is factored into the prioritization actions to address <i>Legionella</i> control	1) Infectious Diseases and Infection Prevention & Control			

The information in these charts is notional and does not necessarily represent how facilities should rate or address these example risks