

# US DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

## **VETERANS HEALTH ADMINISTRATION**

VHA Should Continue to Improve Water Safety and Oversight of Prevention Practices to Minimize the Effects of *Legionella* 

Audit 22-03247-198 October 3, 2023



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## **Executive Summary**

The Veterans Health Administration (VHA) is America's largest integrated healthcare system, providing care for approximately six million veterans each year. About 70 percent of these veterans are over 50 years of age and, according to the Centers for Disease Control and Prevention (CDC), have an increased risk of Legionnaires' disease, a serious type of pneumonia. Legionnaires' disease is caused by *Legionella* bacteria, found naturally in freshwater environments. The bacteria can become a health concern when spread through showerheads, faucets, ice machines, and hot water tanks in the water systems of large buildings. A 2017 CDC report concluded that one in every four people with healthcare-associated Legionnaires' disease dies.<sup>2</sup>

The CDC and VHA have both recognized the importance of implementing control measures to minimize bacterial growth and disease transmission in potable water systems.<sup>3</sup> Without control measures, along with regular water quality monitoring, testing, and remediation, *Legionella* growth could put veterans and employees at risk of illness and death.

VHA Directive 1061 establishes standards for the prevention and control of healthcare-associated Legionnaires' disease at VHA-owned buildings where patients, residents, visitors, or staff stay overnight.<sup>4</sup> Appendix A of this report provides additional detail on the history and previous versions of VHA Directive 1061. The VA Office of Inspector General (OIG) conducted this audit to assess whether VHA is effectively addressing the prevention and control of *Legionella* in compliance with the VHA directive for potable water distribution systems. Specifically, the audit team evaluated whether four selected medical facilities were meeting water safety standards for potable water distribution systems. Appendix B of this report provides additional details on the scope and methodology employed by the OIG.

<sup>&</sup>lt;sup>1</sup> "Legionella" (Legionnaires' Disease and Pontiac Fever), Causes, How it Spreads, and People at Increased Risk" (web page), CDC, accessed March 7, 2023, <a href="https://www.cdc.gov/legionella/about/causes-transmission.html">https://www.cdc.gov/legionella/about/causes-transmission.html</a>. While the VHA directive uses the term "Legionella" disease," the severe illness caused by Legionella bacteria is Legionnaires' disease. This report uses the term Legionnaires' disease for clarity.

<sup>&</sup>lt;sup>2</sup> US Department of Health and Human Services, Centers for Disease Control and Prevention, "Vital Signs: Health Care–Associated Legionnaires' Disease Surveillance Data from 20 States and a Large Metropolitan Area," *Morbidity and Mortality Weekly Report (MMWR)* 66, no. 22 (June 9, 2017).

<sup>&</sup>lt;sup>3</sup> "Controlling *Legionella* in Potable Water Systems" (web page), CDC, accessed March 8, 2023, <a href="https://www.cdc.gov/Legionella/wmp/control-toolkit/potable-water-systems.html">https://www.cdc.gov/Legionella/wmp/control-toolkit/potable-water-systems.html</a>. "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." VHA Directive 1061, *Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems*, February 16, 2021.

<sup>&</sup>lt;sup>4</sup> VHA Directive 1061, *Prevention of Health Care-Associated* Legionella *Disease and Scald Injury from Water Systems*, February 16, 2021.

#### What the Audit Found

The OIG determined that the four VA medical facilities reviewed—in Salem, Virginia; Brooklyn, New York; Pittsburgh, Pennsylvania; and Dublin, Georgia—did not comply with VHA requirements on components of their healthcare-associated *Legionella* disease prevention plans, water safety testing validation collection, remediation actions, and reporting practices. VHA leaders also did not receive complete water safety test results needed to perform effective prevention oversight. Additionally, VA medical facility leaders responsible for notifying clinical staff of *Legionella* detection in routine water samples did not communicate positive test results to staff to ensure clinical awareness for diagnostic testing. Specifically, the OIG found issues in these areas: incomplete healthcare-associated *Legionella* disease prevention plans; inconsistent water sampling; noncompliance with remediation actions; and inconsistent test result reporting.

## Incomplete Healthcare-Associated *Legionella* Disease Prevention Plans

The audit team determined that two of four reviewed facilities were missing at least two of the six prevention plan components required by VHA Directive 1061. These medical facilities did not perform risk assessments for each building included in their healthcare-associated *Legionella* disease prevention plans or establish "dead leg" prevention plans. "Dead legs" in a facility's water system can occur when plumbing fixtures have been altered or capped and the pipe leading to the supply line has not been removed. The stagnant water in dead legs provides an environment that increases the likelihood of *Legionella* growth. Dead leg prevention plans are used to identify and assess risks, as well as prioritize and schedule the elimination of dead legs in a facility's water system. The incomplete healthcare-associated *Legionella* disease prevention plans occurred because Veterans Integrated Services Network (VISN) officials did not provide effective oversight and review processes to ensure directive compliance. The VHA directive requires VA medical center and VISN-level officials to review healthcare-associated *Legionella* 

<sup>&</sup>lt;sup>5</sup> The audit team selected facilities using VHA Water Safety Management Tool data for the audit period of April 1, 2021, through March 31, 2022. The four facilities reviewed were selected from each category based on the following factors: missing test results, positive tests reported, facilities reporting zero Legionella detected, and the facility's Bed Days of Care.

<sup>&</sup>lt;sup>6</sup> VHA Directive 1061, app. A, outlines six components that VA medical facilities are required to include in these healthcare-associated *Legionella* disease building prevention plans: (a) schematic diagrams of the potable water systems; (b) a risk assessment; (c) identification of water system management points where monitoring and controls are implemented; (d) engineering controls, including a dead leg control, elimination, and prevention plan; (e) documentation showing when each water quality and control measure is monitored for condition compliance and corrective action taken; and (f) validation that the control measures are effectively inhibiting Legionella growth.

<sup>&</sup>lt;sup>7</sup> VHA Directive 1061 defines this as a "dead leg control, elimination, and prevention plan," but it will be referred to as a "dead leg prevention plan" in this report.

disease prevention plans' accuracy and completeness but does not prescribe any certification procedures for VISNs to confirm the reviews are consistent and documented.

## Legionella Water Sampling Requirements Not Consistently Followed

The audit team determined that none of the reviewed medical facilities consistently complied with water collection sample requirements from VHA Directive 1061 because the facilities and VISN lacked oversight to ensure those responsible for collecting water samples were properly drawing all samples and testing all required sample outlets. Reviewed medical facilities did not take pure cold water or pure hot water test samples because medical facility staff were either not aware of the directive requirements or did not realize that they did not complete all samples required.

Additionally, the audit team found that the healthcare-associated *Legionella* disease prevention plans at two of four facilities had outdated water sampling requirements from a previous version of the VHA directive, which resulted in the facilities not testing all required sample types or ensuring samples were taken without first flushing the tap, a process known as first draw. During the audit period, there was no action taken by the VISN to ensure that medical facilities, when conducting or contracting for water testing services, were following these requirements.

### **Noncompliance with Remediation Actions**

The audit team reviewed the laboratory reports for all four facilities during the audit period and determined that there was a total of 173 positive *Legionella* samples at three of the facilities. <sup>10</sup> Two of the four facilities, VA medical centers in Salem, Virginia, and Brooklyn, New York, accounting for 170 of the water samples with positive levels of the *Legionella pneumophila* bacteria species, did not conduct all required post-remediation tests. VHA Directive 1061 requires facilities to repeat remediation and retesting steps until water samples test below a *Legionella* level of one colony-forming unit per milliliter (CFU/ml). The audit team found that the facilities conducted only 11.2 percent of the required post-remediation tests for these positive *Legionella* test results.

The VA medical centers in Salem, Virginia, and Dublin, Georgia, also did not conduct repeat remediation actions as required by the directive, with one facility having elevated *Legionella pneumophila* species levels in its post-remediation test results. The audit team determined that

<sup>&</sup>lt;sup>8</sup> VHA Directive 1061 defines an outlet as a point in the potable water distribution system where an individual accesses the water.

<sup>&</sup>lt;sup>9</sup> VHA Directive 1061, *Prevention of Health Care-Associated* Legionella *Disease and Scald Injury from Potable Water Distribution Systems*, August 13, 2014.

<sup>&</sup>lt;sup>10</sup> For the purposes of this report, the term "positive" means water samples showing *Legionella* bacteria at a concentration of one colony-forming unit per milliliter or greater.

contributing to the post-remediation testing requirements not being met was the lack of clarity in the responsibilities section of directive 1061 for identifying which staff are responsible for remediation action completion.

## Persistent Legionella despite Efforts to Comply with Directive Requirements

The team found that the VA medical center in Salem continued to experience persistent positive *Legionella* growth despite demonstrated efforts to comply with VA Directive 1061 remediation and mitigation requirements, including previously implementing all of the minimum remediation actions required to mitigate potential *Legionella* risk. During the audit period, the facility decided to discontinue remediation actions for two quarters, and, for the remaining two quarters, conduct limited remediation, despite positive test results greater than 1 CFU/ml. Despite these persistent positive environmental *Legionella* testing results, records from the Inpatient Evaluation Center data management system reflected that no healthcare-associated Legionnaires' disease cases were identified or reported for the Salem VA medical center during the audit period from April 1, 2021, through March 31, 2022.<sup>11</sup>

The facility has reported approximately a 53 percent rate of identified *Legionella* bacteria in water samples in nine buildings over the past seven years, despite conducting hyperchlorination and thermal remediation efforts to mitigate potential *Legionella* risk and utilizing point-of-use filters and routine flushing of hot and cold water at outlets in an attempt to access or prevent *Legionella* growth in building water distribution systems.

## Improved Communication Needed with Oversight Officials When Facility Staff Have Difficulty Conducting Required Remediation Actions

The audit team reviewed all positive *Legionella* water testing samples and associated remediation actions conducted for the four facilities reviewed and found lapses in communication regarding remedial actions with officials responsible for conducting oversight and consultation. For example, during the audit period, the Salem VA medical center, which faced persistent positive *Legionella* in its water system, did not attempt to use hyperchlorination or thermal remediation to lower *Legionella* levels in areas of buildings that had 133 of the facility's 144 positive *Legionella pneumophila* species samples (about 92 percent). According to the facility management chief, staff did not perform remediation steps in these areas because of continued challenges to lower or eradicate persistent *Legionella* even when following the remediation steps outlined in VHA Directive 1061. The director of VHA's Office of Healthcare

<sup>&</sup>lt;sup>11</sup> The Inpatient Evaluation Center (IPEC) is the official repository for *Legionella* clinical information and *Legionella* case report data. The IPEC data management system is an internal VA website, not available for public viewing, which contains facility-reported data on infections.

Engineering (OHE) was not made aware of the facility decision to not conduct consistent remediation on all *Legionella*-positive samples, or the facility's challenges with minimal success rates. The director of OHE stated that medical facilities should continue remediation efforts whenever they have a positive *Legionella* result in quarterly testing. If facilities continue to face challenges with remediation efforts, the OHE director expected he would receive issue briefs or other communication from VISN offices to trigger OHE involvement in addressing the problem. Directive 1061 instructs the VISN water safety liaison to coordinate communication between VHA central office and VISN or VA medical facility staff regarding water safety and *Legionella* prevention actions, policies, guidance, or events. However, the audit team did not find any specific language in the directive that conveyed these expectations for communication through issue briefs or the requirement for VISN officials to communicate challenges specific to remediation at all management levels. Despite this lack of specificity, VHA Directive 1061 does describe that OHE is available to consult with VISNs and medical facilities for guidance on remediation. Therefore, it is incumbent on facility and VISN officials to collaborate and communicate any challenges faced when complying with required remediation practices.

## Complete Quarterly *Legionella* Testing Results Not Reported or Communicated

VHA Directive 1061 requires that all environmental *Legionella* test results, including routine and post-remediation testing, be reported in the VHA Water Safety Management Tool (WSMT) database. The VISN water safety liaison is responsible for analyzing and validating WSMT data to confirm medical facilities are complying with reporting requirements. The audit team found that VISN and VHA oversight officials were not consistently receiving quarterly *Legionella* test results for all four facilities reviewed. The team determined that this occurred because the VISN water safety liaisons for three facilities reviewed did not provide adequate oversight of VA medical facility directors to ensure compliance with the reporting requirements.

VHA Directive 1061 also requires that the medical facility chief of staff and associated director of patient care services coordinate to communicate all positive *Legionella* water sample results from quarterly testing to clinical staff involved in direct patient care. The audit team noted that two of the four VA medical facilities did not communicate any positive *Legionella* test results to clinical staff. In addition, the audit team observed one facility that alerted the clinical staff only when the facility water test results were positive for *Legionella pneumophila* serogroup 1,

<sup>&</sup>lt;sup>12</sup> The VHA WSMT is an internal VA website used as a repository to report and document water sampling of VHA-owned buildings; *Legionella pneumophila* is divided into 15 serogroups (bacteria with a common antigen), among which serogroup 1 is the most prevalent disease-causing variant. Qi Zhang et al., "Legionnaires' Disease Caused by Legionella pneumophila Serogroups 5 and 10, China," *Emerging Infectious Diseases* 20, no. 7 (July 2014):1242–1243, https://wwwnc.cdc.gov/eid/article/20/7/13-1343 article.

<sup>&</sup>lt;sup>13</sup> VHA Directive 1061, *Prevention of Health Care-Associated* Legionella *Disease and Scald Injury from Water Systems*, February 16, 2021.

instead of notifying clinical staff for all *Legionella* species and serogroup positive test samples as required by the directive. The required clinical notifications did not occur because the VISN director did not provide adequate oversight to make certain that all VA medical facilities within the VISN comply with the directive for prevention of Legionnaires' disease, including communication of positive *Legionella* results.

#### What the OIG Recommended

The OIG made eight recommendations. The first two recommendations were addressed to the assistant under secretary for health for support:

- Establish certification procedures for VISNs to ensure medical facility healthcare-associated *Legionella* disease prevention plans comply with Veterans Health Administration Directive 1061.
- Develop quality control and quality assurance checks to ensure the VISNs fulfill their requirements for oversight and enforcement of Veterans Health Administration Directive 1061 quarterly *Legionella* water testing procedures.

The OIG made two recommendations to the assistant under secretary for health for operations:

- Monitor VISN officials to ensure fulfillment of their oversight responsibilities found in Veterans Health Administration Directive 1061 regarding *Legionella* water sampling, testing, remediation efforts, and reporting of testing data, including postremediation test results.
- Take actions to confirm that VISN officials are ensuring front-line staff are
  routinely notified by responsible medical facility officials when elevated *Legionella*water sample levels require diagnostic awareness and additional clinical
  surveillance of veterans to detect Legionnaires' disease.

The OIG made four recommendations to the director of the Office of Healthcare Engineering:

- Consider alternative measures, such as adding dedicated resources to provide expertise and support for medical facilities experiencing persistent positive *Legionella* in facility water supply systems after applying the remediation efforts prescribed by Veterans Health Administration Directive 1061.
- Assist the Salem VA medical center with persistent positive *Legionella* in the facility water supply system, and, with consideration of the ongoing water supply system renovations, develop an action plan to mitigate remediation challenges.
- Clarify the responsibility section of Veterans Health Administration Directive 1061 to clearly define oversight responsibilities for ensuring required remediation steps are completed when facilities receive positive *Legionella* water test results.

• Revise the Water Safety Management Tool to alert VISN and medical facility oversight officials when quarterly testing data are not posted.

## **VA Comments and OIG Response**

The under secretary for health concurred or concurred in principle with all the report's recommendations and submitted responsive action plans for each. Appendix C provides the full text of the under secretary's comments. Overall, the OIG considers the proposed corrective measures in the VHA action plan submitted by the under secretary for health to be responsive to the recommendations. The OIG will monitor execution of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating progress addressing the issues identified.

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## **Abbreviations**

CDC Centers for Disease Control and Prevention

CFU/ml colony-forming unit per milliliter

FMS facility management services

FY fiscal year

OHE Office of Healthcare Engineering

OIG Office of Inspector General

VHA Veterans Health Administration

VISN Veterans Integrated Service Network

WSMT Water Safety Management Tool



## Introduction

The Veterans Health Administration (VHA) is America's largest integrated healthcare system and provides care for approximately six million veterans each year at about 1,300 healthcare facilities. Approximately 70 percent of these veterans are 50 years of age or older, and 87 percent of them are male. Both the age range and gender are population factors that carry a higher risk of Legionnaires' disease, a serious type of pneumonia. A 2017 Centers for Disease Control and Prevention (CDC) report from 20 states and one large metropolitan area concluded that one in every four people with healthcare-associated Legionnaires' disease dies.

Legionnaires' disease is caused by exposure to *Legionella* bacteria. There are many internal, external, and environmental factors that encourage *Legionella* bacteria growth, including construction, water main breaks, biofilm, water temperature or pH fluctuations, inadequate levels of disinfectant, and water stagnation. <sup>17</sup> Studies have shown that weather conditions can also increase *Legionella* illnesses, particularly in areas with wet, humid weather; increased rainfall; and warm summer months. <sup>18</sup> Additionally, aging centralized water systems and piping used beyond its expected lifespan increase the risk for main breaks and intrusion, corrosion-enhanced

<sup>&</sup>lt;sup>14</sup> "Veteran Population, Population Tables" (web page), VA National Center for Veterans Analysis and Statistics, accessed March 27, 2023, <a href="https://www.va.gov/vetdata/Veteran">https://www.va.gov/vetdata/Veteran</a> Population.asp.

<sup>15 &</sup>quot;Legionellosis, Key Facts" (web page), World Health Organization, accessed March 7, 2023, <a href="https://www.who.int/news-room/fact-sheets/detail/legionellosis">https://www.who.int/news-room/fact-sheets/detail/legionellosis</a>; "Causes, How it Spreads, and People at Increased Risk" (web page), Centers for Disease Control and Prevention, accessed March 7, 2023, <a href="https://www.cdc.gov/Legionella/about/causes-transmission.html">https://www.cdc.gov/Legionella/about/causes-transmission.html</a>. While VHA's directive uses the term "Legionnaires" disease. This report uses the term Legionnaires' disease for clarity.

<sup>&</sup>lt;sup>16</sup> US Department of Health and Human Services, Centers for Disease Control and Prevention, "Vital Signs: Health Care—Associated Legionnaires' Disease Surveillance Data from 20 States and a Large Metropolitan Area," *Morbidity and Mortality Weekly Report (MMWR)* 66, no. 22 (June 9, 2017).

<sup>&</sup>lt;sup>17</sup> Biofilm is a collection of inorganic and organic matter that accumulates on surfaces such as water pipes, outlets, and other equipment in water systems.

<sup>&</sup>lt;sup>18</sup> David N. Fisman, et al., "It's Not the Heat, It's the Humidity: Wet Weather Increases Legionellosis Risk in the Greater Philadelphia Metropolitan Area," *Journal of Infectious Diseases* 192, no. 12 (December 15, 2005), <a href="https://academic.oup.com/jid/article/192/12/2066/839374">https://academic.oup.com/jid/article/192/12/2066/839374</a>; Barry S. Fields, Robert F. Benson, Richard E. Besser, "*Legionella* and Legionnaires' Disease: 25 Years of Investigation." *Clinical Microbiology Reviews* 15, no. 3 (July 1, 2002): 506–526, <a href="https://journals.asm.org/doi/full/10.1128/CMR.15.3.506-526.2002">https://journals.asm.org/doi/full/10.1128/CMR.15.3.506-526.2002</a>; L.A. Hicks, et al., "Increased rainfall is associated with increased risk for legionellosis," *Epidemiology and Infection* 135, no. 5 (July 2007): 811–817, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2870637/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2870637/</a>; Barbara J. Marston, MD; Harvey B. Lipman, PhD; Robert F. Breiman, MD, "Surveillance for Legionnaires' Disease. Risk Factors for Morbidity and Mortality," *Archives of Internal Medicine* 154, no. 21 (November 14, 1994): 2417–2422,

https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/619597; Albert E. Barskey, Gordana Derado, and Chris Edens. "Rising Incidence of Legionnaires' Disease and Associated Epidemiologic Patterns, United States, 1992–2018," *Emerging Infectious Diseases* 28, no. 3 (March 2022): 527–538, https://doi.org/10.3201/eid2803.211435.

biofilm development, and colonization with *Legionella*.<sup>19</sup> The CDC acknowledges there is no known safe level of *Legionella* bacteria in building water systems, and both the CDC and VHA have recognized the importance of implementing control measures that create environmental conditions to minimize growth and transmission in potable water systems.<sup>20</sup>

The CDC has also recognized that healthcare facilities are at a higher risk for Legionnaires' disease and outbreaks because they treat a population of immunocompromised hospitalized patients and often have large complex water systems that, if not properly maintained, can contribute to the growth of *Legionella*. VA has faced past occasions of identified *Legionella* bacteria in its medical facilities' water systems, as well as confronted prominent healthcare-associated Legionnaires' disease outbreaks at medical facilities that resulted in patient illness and death. VA's history with Legionnaires' disease, the aging infrastructure of many medical facilities, and patient population risk factors prompted this assessment.

The VA Office of Inspector General (OIG) conducted this audit to assess whether VHA is effectively addressing the prevention and control of *Legionella* in compliance with Directive 1061.<sup>22</sup> Specifically, the audit team evaluated whether the four selected medical facilities were meeting VA's water safety and reporting standards for potable water distribution systems. Appendix B of this report provides additional details on the scope and methodology employed by the OIG.

## Legionella and Legionnaires' Disease

Infections caused by *Legionella* bacteria have been clinically recognized since it was first discovered after a 1976 outbreak that led to several deaths.<sup>23</sup> Human disease caused by *Legionella* is referred to as legionellosis, which primarily consists of two diseases: Legionnaires' disease, a serious and potentially fatal infection of the lungs and other organs, and Pontiac fever,

<sup>&</sup>lt;sup>19</sup> "Diagnosis, Ecology, and Exposure Pathways," chap. 2 in *Management of Legionella in Water Systems* (Washington, DC: The National Academies Press, 2020), 34, https://nap.nationalacademies.org/catalog/25474/management-of-legionella-in-water-systems.

<sup>&</sup>lt;sup>20</sup> "Controlling Legionella in Potable Water Systems" (web page), CDC, accessed March 8, 2023, <a href="https://www.cdc.gov/Legionella/wmp/control-toolkit/potable-water-systems.html">https://www.cdc.gov/Legionella/wmp/control-toolkit/potable-water-systems.html</a>. "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." VHA Directive 1061, Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems, February 16, 2021.

<sup>&</sup>lt;sup>21</sup> Refer to appendix A of this report for details of previous occasions of *Legionella* at VA facilities, including those discussed in prior VA OIG reports.

<sup>&</sup>lt;sup>22</sup> VHA Directive 1061, *Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems*, February 16, 2021. Unless otherwise noted throughout the report, "policy" refers to this directive.

<sup>&</sup>lt;sup>23</sup> "Legionella—History, Burden, and Trends" (web page), CDC, accessed March 9, 2023, <a href="https://www.cdc.gov/Legionella/about/history.html">https://www.cdc.gov/Legionella/about/history.html</a>; Ronnie Henry, "Etymologia: *Legionella pneumophila*," <a href="https://wwwnc.cdc.gov/eid/article/23/11/et-2311">Emerging Infectious Diseases 23</a>, no. 11 (November 2017): 1851, <a href="https://wwwnc.cdc.gov/eid/article/23/11/et-2311">https://wwwnc.cdc.gov/eid/article/23/11/et-2311</a> article.

a less severe illness that resolves without medical treatment.<sup>24</sup> Both diseases most commonly occur after inhalation of contaminated water droplets.

Legionella is a bacteria found naturally in freshwater environments, like lakes and streams, though it is generally not present in large enough numbers to cause disease. The bacteria can become a health concern when they multiply to uncontrolled or poorly controlled levels and spread in human-made water systems, such as large buildings with complex water systems, showerheads, faucets, ice machines, and hot water tanks and heaters. Legionella grows best within a certain temperature range (77°F–113°F); when stagnation occurs in building water systems; and when external factors, such as construction, water main breaks, and changes in municipal water quality, affect the water entering a building.<sup>25</sup>

There are at least 60 different species of *Legionella*, most of which cause infection, particularly in immunocompromised or high-risk patients.<sup>26</sup> However, most of the disease—approximately 90 percent of cases—is caused by the *Legionella pneumophila* species.<sup>27</sup>

Given how widespread *Legionella* appears in nature, and considering the various factors and complexities associated with Legionnaires' disease, 100 percent prevention of *Legionella* in water supply systems is not possible. However, prevention and control measures can reduce the risk of exposing people to *Legionella* in building and non-potable water systems. If control measures, such as regular monitoring of water quality parameters (temperature, PH, and biocide levels), validation efforts including routine *Legionella* testing, and response efforts such as water treatment and remediation are not properly or routinely conducted, *Legionella* growth could persist, putting veterans and employees at VA facilities at risk of illness or death.<sup>28</sup>

#### VA Efforts and VHA Directive 1061

The veteran population is acutely sensitive to this hazard, as the VHA healthcare system has a patient population predominately over 50 years of age, and VA medical facilities offer a range of

<sup>&</sup>lt;sup>24</sup> "Legionellosis" (web page), World Health Organization, accessed March 7, 2023, <a href="https://www.who.int/news-room/fact-sheets/detail/legionellosis">https://www.who.int/news-room/fact-sheets/detail/legionellosis</a>. Pontiac fever (also called Pontiac disease) is a non-pneumonic disease caused by Legionella exposure and is an "acute, self-limiting influenza-like illness usually lasting 2–5 days." No deaths have been associated with this type of infection, and it "does not require medical interventions, including antibiotic treatment." VHA Directive 1061 establishes policy for the prevention and control of healthcare-associated Legionnaires' disease; therefore, this audit focused on the same disease and did not assess Pontiac fever.

<sup>&</sup>lt;sup>25</sup> "Legionella Disease Specifics—Etiologic Agent and Transmission" (web page), CDC, accessed March 9, 2023, <a href="https://www.cdc.gov/Legionella/clinicians/disease-specifics.html">https://www.cdc.gov/Legionella/clinicians/disease-specifics.html</a>.

<sup>&</sup>lt;sup>26</sup> "Legionella Disease Specifics—Etiologic Agent and Transmission," CDC.

<sup>&</sup>lt;sup>27</sup> Natalia A Kozak-Muiznieks, et al. "Prevalence of sequence types among clinical and environmental isolates of *Legionella pneumophila* serogroup 1 in the United States from 1982 to 2012," *Journal of Clinical Microbiology* 52, no. 1 (January 2014): 201–211. *Legionella pneumophila* is divided into 15 serogroups, among which serogroup 1 is the most prevalent disease-causing variant. Qi Zhang et al., "Legionnaires' Disease Caused by Legionella pneumophila Serogroups 5 and 10, China."

<sup>&</sup>lt;sup>28</sup> A biocide is a chemical agent or substance that can deter, inactivate, or kill microorganisms.

services, such as surgery, cancer care, and organ transplants, where many immunocompromised veterans receive care. In June 2018, the VHA National Infectious Diseases Service published an epidemiology study intended to assess the amount of Legionnaires' disease with VA exposure versus community exposure.<sup>29</sup> The study acknowledges that VA has prioritized Legionnaires' disease prevention by establishing an internal policy aimed to limit *Legionella* growth in water distribution systems. Findings indicated the number of Legionnaires' disease cases with VHA patients and/or residents with an overnight stay was very low, with significantly decreasing rates over the period of years evaluated in the study. It also suggested that prevention efforts may have contributed to improved patient safety and indicated the importance of *Legionella* prevention programs in long-term care settings. The study also found that the highest percentage of positive cases of Legionnaires' disease occurred in the summer months and in the East North Central region.

The CDC and VHA Directive 1061 define individuals at increased risk of getting sick with Legionnaires' disease as those who

- are over 50 years old,
- are current or former smokers,
- have weakened immune systems, or
- have chronic lung conditions.

VHA convened a multidisciplinary expert working group in 2007 to establish risk management policy to address primary prevention and control of healthcare-associated Legionnaires' disease at VHA inpatient facilities. In February 2008, VHA implemented Directive 2008-010, for the prevention of healthcare-associated Legionnaires' disease at VHA inpatient facilities. In 2014, VHA published this policy under Directive 1061, which was later updated in 2021 and 2022, for the prevention and control of healthcare-associated Legionnaires' disease from water systems in VA-owned buildings. (The directive also addresses outdoor non-potable, aerosol-generating water systems; however, these are not in the scope of the audit objective and therefore will not be discussed in this report.) Appendix A of this report provides additional detail on the history of VHA Directive 1061.

## **Roles and Responsibilities**

Figure 1 lists the individuals and offices that oversee and perform the prevention and control of healthcare-associated Legionnaires' disease in VHA, according to the directive. Appendix A of

<sup>&</sup>lt;sup>29</sup> Shantini D. Gamage, PhD, MPH; Meredith Ambrose, MHA; Stephen M. Kralovic, MD, MPH; Loretta A. Simbartl, MS; Gary A. Roselle, MD, "Legionnaires Disease Surveillance in US Department of Veterans Affairs Medical Facilities and Assessment of Health Care Facility Association," *JAMA Network Open 1*, no. 2 (June 15, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6324594/.

this report provides additional detail on Office of Healthcare Engineering (OHE) responsibilities from VHA Directive 1061.

#### Overarching Governance

- Assistant Under Secretary for Health for Operations
- VHA Office of Healthcare Engineering (OHE)
- · Director of the National Infectious Diseases Service

#### Healthcare-Associated *Legionella* Disease Prevention Plans

- Veterans Integrated Service Network (VISN) Director
- VISN Water Safety Liaison
- VA Medical Facility Director
- · VA Medical Facility Chief of Engineering
- Facility Water Safety Committee

#### Water-Testing Process

- VA Medical Facility Director
- Facility Water Safety Committee
- VISN Water Safety Liaison

#### Remediation Process

· Facility Water Safety Committee

#### Notification of Positive Samples

VA Medical Facility Chief of Staff and Associate Director of Patient Care Services

Figure 1. Individuals and offices involved in the compliance of VHA Directive 1061.

Source: OIG analysis of roles and responsibilities described in VHA Directive 1061.

For overarching governance, the **assistant under secretary for health for operations** is responsible for communicating the contents of the directive to each of the Veterans Integrated Services Networks (VISNs); assisting VISN directors with resolving implementation and

compliance challenges in all VA medical facilities within that VISN; and providing oversight of VISNs to ensure compliance with the directive.<sup>30</sup>

The VHA Office of Healthcare Engineering (OHE) is a subordinate organization under Healthcare Environment and Facilities Programs. The director of OHE is responsible for the engineering aspects of the directive and providing as-needed consultative assistance. Additionally, the director is responsible for administering the Water Safety Management Tool (WSMT) for the collection of *Legionella* data to facilitate analysis and action.<sup>31</sup>

As to healthcare-associated *Legionella* disease prevention plans, the **VISN directors** are responsible for ensuring that all VA medical facilities within the VISN comply with the directive and that annual healthcare-associated *Legionella* disease prevention plans are completed, including annual recertification, reporting requirements, and clinical and water testing. The **VISN water safety liaison** is responsible for obtaining and reviewing annual healthcare-associated *Legionella* disease prevention plans, reports, and clinical and water testing from all VA medical facilities within the VISN. The VISN water safety liaison is also responsible for reviewing and validating WSMT data, and well as consulting with VA medical facilities to improve performance.

The VA medical facility director is responsible for establishing a VA medical facility Legionnaires' disease prevention policy in alignment with VHA Directive 1061. Additionally, the director's responsibilities include approving healthcare-associated *Legionella* disease prevention plans, ensuring that all water testing for *Legionella* is conducted in accordance with the directive, and that the quarterly and post-remediation test results are submitted to the WSMT.

The **facility water safety committee chair** is responsible for developing and reviewing written healthcare-associated *Legionella* disease prevention plans at least annually for buildings. This role is also responsible for establishing the plan for conducting water testing for *Legionella*, determining the water samples to be tested, and conducting routine committee meetings at least quarterly. These quarterly meetings include discussion of water test results and remedial actions where *Legionella* was detected, review of whether healthcare-associated *Legionella* disease prevention plan(s) need to be updated, and assessment of documented verification confirming policy implementation. Additionally, the committee discusses if any additional actions are necessary where the *Legionella* detected was not *Legionella pneumophila* or was *Legionella pneumophila* at less than 1 CFU/ml.<sup>32</sup>

<sup>&</sup>lt;sup>30</sup> VHA divides the United States into 18 regional networks, known as VISNs, which manage day-to-day functions of medical centers and provide administrative and clinical oversight.

<sup>&</sup>lt;sup>31</sup> The WSMT is an internal VA website used as a repository to report and document water sampling of VHA-owned buildings.

<sup>&</sup>lt;sup>32</sup> For the purposes of this report, the term "positive" means water samples showing *Legionella* bacteria at a concentration of one colony-forming unit per milliliter (CFU/ml) or greater.

For the water testing process and remediation, the **facility water safety committee** is responsible for determining the extent of remediation needed for water samples that tested positive in different areas of the building.

For notification of positive samples, the VA medical facility chief of staff and VA medical facility associate director of patient care services are responsible for collaborating to ensure that clinical staff involved in direct patient care are notified in a timely manner when routine water testing is positive for *Legionella*, to increase diagnostic awareness.

### Healthcare-Associated Legionella Disease Prevention Plans

VA medical facilities must establish and implement a healthcare-associated *Legionella* disease prevention plan for each building in which patients, residents, visitors, or employees stay overnight.<sup>33</sup> VHA Directive 1061 requires that these prevention plans include six primary components for each building at the facility under the purview of the directive:

- 1. Schematic diagrams of the potable water systems
- 2. Risk assessment(s)
- 3. Identification of water system management points where monitoring and controls are implemented
- 4. Establishment of engineering control strategies, specifically
  - a. System limits to inhibit Legionella
  - b. Equipment and methods used to prevent scald injury
  - c. A schedule for routine monitoring of controls
  - d. Dead leg control, elimination, and prevention plans <sup>34</sup>
- 5. Defining and documenting when each water quality and control measure is monitored for condition compliance, as well as corrective action(s) taken
- 6. Validation that the control measures are effectively inhibiting *Legionella* growth

The VA medical facility director is responsible for ensuring each building that needs one has a written, approved healthcare-associated *Legionella* disease prevention plan.

<sup>&</sup>lt;sup>33</sup> Healthcare-associated *Legionella* disease prevention plans, required by appendix A of VHA Directive 1061, will also be referred to as "prevention plans" in this report.

<sup>&</sup>lt;sup>34</sup> Dead legs in a facility's water system can occur when plumbing fixtures have been altered or capped instead of removing the pipe back to its supply line. Dead legs cause areas of stagnant water, providing an environment that increases the likelihood of *Legionella* growth.

### Legionella Testing

In addition, VHA Directive 1061 requires quarterly testing of building potable water distribution systems to validate that the engineering controls are successfully inhibiting growth of *Legionella*.<sup>35</sup> Pursuant to the Directive 1061 as updated in 2021, routine testing of water distribution systems for *Legionella* requires 20 samples from water outlets as follows:<sup>36</sup>

- At least two samples from an ice machine or other pure cold water source
- At least two samples from a pure hot water source, if such outlets are available
- The remainder of the samples from mixed water samples taken by first draw whenever a mixing valve is in place at the outlet<sup>37</sup>

### Legionella Remediation

The directive also mandates that VA medical facilities implement remedial actions to mitigate potential *Legionella* risk when routine quarterly testing detects *Legionella pneumophila* at a concentration of 1 CFU/ml or greater. However, based on facility building risk assessments, the directive also gives the facility water safety committee the responsibility to potentially initiate remediation in areas of buildings where *Legionella* detected was not *Legionella pneumophila* or was *Legionella pneumophila* at less than 1 CFU/ml.<sup>38</sup> For areas of a building with individuals considered at high risk for infection, remediation must occur if testing detects any amount of any *Legionella* species.<sup>39</sup>

The directive outlines two approaches to remediation: (1) thermal remediation, a process of temporarily setting the temperature in the hot water distribution system to  $160^{\circ}F-170^{\circ}F$  and then continuously flushing each outlet in the system for at least 30 minutes, and (2) hyperchlorination, which involves injecting chlorine at an elevated level in the hot and/or cold water distribution systems and maintaining that level throughout the systems for at least two hours before flushing all outlets. After remediation is complete, VA medical facilities are required to wait at least 24 hours and then retest the water in the areas that tested positive. If the remediation was successful, then the quarterly testing cycle for *Legionella* is complete. VA medical facilities are

<sup>&</sup>lt;sup>35</sup> VHA Directive 1061. Engineering controls are prevention practices put in place to inhibit *Legionella* growth in the potable water distribution systems of buildings required to be tested for *Legionella*. Primary engineering controls discussed in Directive 1061 include maintenance of water temperatures and biocide levels.

<sup>&</sup>lt;sup>36</sup> VHA Directive 1061 defines an outlet as a point in the potable water distribution system where an individual accesses the water.

<sup>&</sup>lt;sup>37</sup> A first-draw sample is collected without flushing the tap first.

<sup>&</sup>lt;sup>38</sup> VHA Directive 1061, *Prevention of Health Care-Associated* Legionella *Disease and Scald Injury from Water Systems*, February 16, 2021.

<sup>&</sup>lt;sup>39</sup> VHA Directive 1061 defines high-risk individuals as those with a compromised immune system (for example, due to transplant, malignancy, renal disease, or diabetes); the following examples are listed in the directive for building functions associated with increased risk: transplant units, protective environments, and hematology-oncology units.

required to repeat remediation and retesting until efforts are successful at reducing levels of *Legionella* positivity, per the requirements in the directive.

### Communication and Data Reporting of Legionella Test Results

The VA medical facility chief of staff, the associate director for patient care services, the facility water safety committee chair, the infection prevention and control committee, and the facility chief engineer or the facility manager must be immediately notified of any positive *Legionella* routine testing or post-remediation validation test results by the individual(s) assigned to receive and report all water samples.

Clinicians involved in direct patient care must also be notified of the positive *Legionella* water test results, including the species and serogroup detected (if appropriate), to implement heightened awareness for clinical testing for Legionnaires' disease. If *Legionella* is found during testing, clinicians are required to be vigilant for patients who develop respiratory disease or symptoms suggestive of pneumonia during their hospital admission, or while under residential care, and test such identified patients for Legionnaires' disease. This heightened state of clinical vigilance and testing must be followed for at least three months and continued until the next round of quarterly water test results are received. VHA Directive 1061 outlines that the species of *Legionella* detected determines the types of clinical testing recommended. For example, if water sampling detects the *Legionella pneumophila* serogroup 1, clinicians should use both urinary antigen testing and clinical culture of sputum for diagnosis of Legionnaires' disease. The audit team assessed the communication of test results but did not evaluate clinical validation.

VA medical facilities are required to report quarterly *Legionella* test results and post-remediation retest results to the VHA WSMT within one week of receiving the final results from the laboratory. The VISN then has 45 days to certify and lock the data after the end of each quarter.

<sup>&</sup>lt;sup>40</sup> Sputum is the mixture of saliva and mucus that is coughed up from the respiratory tract, often either following an infection or an irritation of the mucosa.

## **Results and Recommendations**

## Finding: VA Medical Facilities Need to Continue to Improve Their Efforts to Reduce *Legionella* Risks to Patients

The OIG found that the four VA medical facilities the team reviewed did not comply with all VHA Directive 1061 requirements regarding healthcare-associated *Legionella* disease prevention plans for each building, water safety testing validation collection requirements, remediation actions, and reporting practices. They also did not consistently communicate positive test results so clinical staff were aware of potential elevated risks to patients.

VA has prioritized Legionnaires' disease prevention by establishing and revising internal policy to improve processes for water sampling and remediation, but some areas still need to be addressed. VA medical facilities' incomplete healthcare-associated *Legionella* disease prevention plans, improper water sampling, unreported testing data, and lack of consistent actions to remediate *Legionella* levels occurred because key VISN officials provided limited reviews and oversight. Additionally, when positive *Legionella pneumophila* test results occur at a medical facility, when *Legionella* is detected in areas of buildings with individuals considered at higher risk for infection, or when building risk assessments deem it necessary for any other *Legionella* levels or species, VHA Directive 1061 requires remediation to mitigate potential *Legionella* risk. However, the responsibilities section of the directive does not clearly define oversight responsibilities for ensuring this required remediation is completed. Additionally, certification procedures need to be created to ensure that VISNs document compliance with all VHA Directive 1061 VISN oversight requirements. Deviating from this directive can affect staff's ability to identify areas of *Legionella* growth for clinical awareness for diagnostic approaches for susceptible patients.

The following issues support the OIG's finding:

- Two of four VA medical facilities reviewed had incomplete healthcare-associated *Legionella* disease prevention plans for their buildings.
- None of the four VA medical facilities consistently followed *Legionella* water sampling requirements.
- Three of the four facilities did not fully comply with necessary remediation actions required to mitigate potential *Legionella* risk.
- None of the VA medical facilities reviewed consistently reported quarterly *Legionella* test results to the VHA Water Safety Management Tool.

#### What the OIG Did

The audit team selected four facilities by grouping facilities within the extracted WSMT data into two main categories during the audit period from April 1, 2021, through March 31, 2022: facilities that detected *Legionella* and facilities that did not detect *Legionella*. The audit team then used a risk-based analysis of the WSMT data to judgmentally select the facilities based on (1) missing reported quarterly test results, (2) number of detected *Legionella*-positive quarterly tests, (3) facilities with no *Legionella* detected consistently throughout the four quarters within the audit period, and (4) the medical facility's Bed Days of Care.<sup>41</sup>

To assess whether selected medical facilities were meeting VA's water safety and reporting standards for potable water distribution systems in compliance with VHA Directive 1061, the audit team reviewed documentation for each facility's buildings under the purview of the directive. This review included

- facility routine water test results for potable water,
- laboratory reports from VA or third-party laboratories for all routine water samples and post-remediation water samples,
- facility mitigation and remediation processes,
- quarterly and annual reports of water system maintenance and monitoring, and
- any applicable issue briefs.

To determine if the facilities selected were meeting water safety standards for potable water distribution systems, the audit team reviewed facility and building healthcare-associated *Legionella* disease prevention plans for the four facilities. The team assessed each plan to identify elements that could affect a facility's testing processes and results and evaluated whether oversight responsibilities were performed for controls and processes to inhibit *Legionella* growth and veterans' potential exposure.

The audit team interviewed facility staff, including the medical facility directors and associate directors, chief engineers, members of each of the facility water safety committees, contracted water testing staff, and facilities maintenance staff who were involved in water testing and remediation. The team also conducted interviews with the VISN director, the VISN capital asset manager, and the VISN water safety committee liaison. In addition, the team conducted multiple interviews with the VHA Office of Healthcare Engineering and the associate director of VHA

<sup>&</sup>lt;sup>41</sup> VHA Handbook 1006.02, *VHA Site Classifications and Definitions*, December 30, 2013. A Bed Day of Care is an overnight stay of an individual in a VHA bed within an assigned treating specialty section.

National Infectious Diseases Services regarding program oversight.<sup>42</sup> The audit team did not evaluate clinical actions taken when *Legionella* was detected at a facility. Appendix B of this report provides additional details on the scope and methodology employed by the OIG.

# Two of Four VA Medical Facilities Reviewed Had Incomplete Healthcare-Associated *Legionella* Disease Prevention Plans for Their Buildings

The audit team determined that two of the facilities examined, the Brooklyn and Dublin VA medical centers, were missing at least two of the six healthcare-associated *Legionella* disease prevention plan components required by VHA Directive 1061. Additionally, the prevention plans at the Dublin and Salem VA medical centers did not contain thorough descriptions of each building's functions and features as required by the directive to develop strategies to control and prevent *Legionella* growth.

The audit team determined that the two medical facilities missing required building prevention plan components were lacking risk assessments and established dead leg prevention plans. <sup>43</sup> Both components are needed to identify factors that can encourage *Legionella* growth, including potential regional implications and aging infrastructure. The VHA directive requires a medical facility to assess buildings annually for factors that may indicate increased risk for Legionnaires' disease, including patient population risk factors; past positive test results; the presence of building functions associated with increased risk, such as a transplant unit; the ability to implement engineering controls to prevent *Legionella* growth; and the location of the building if in an area of the country with recognized higher rates of incidence of Legionnaires' disease.

Dead legs in a facility's water system can occur when plumbing fixtures have been altered or capped and the pipe leading to the supply line has not been removed. The stagnant water in dead legs provides an environment that increases the likelihood of *Legionella* growth. VHA Directive 1061 requires medical facility healthcare-associated *Legionella* disease prevention plans to identify existing dead legs, assess their risk for contributing to *Legionella* growth, create a schedule to remove them, and implement processes to prevent additional dead legs. Table 1 presents the summary of facility compliance with the healthcare-associated *Legionella* disease prevention plan required components.

<sup>&</sup>lt;sup>42</sup> The director of the National Infectious Diseases Service is responsible for developing procedures and guidelines within VHA for *Legionella* prevention in combination with other VHA program offices, as necessary. The director is also responsible for managing and reviewing the centralized collection of Legionnaires' disease case data from VA medical facilities, as well as providing consultative assistance to VISNs and VA medical facilities related to the risk and clinical aspects of Legionnaires' disease and validation requirements.

<sup>&</sup>lt;sup>43</sup> VHA Directive 1061 defines this as a "dead leg control, elimination, and prevention plan," but it will be referred to as a "dead leg prevention plan" in this report.

**Table 1. VHA Directive 1061 Prevention Plan Compliance** 

VHA Directive 1061 prevention plan required components	Salem	Brooklyn	Pittsburgh	Dublin*
Schematic diagrams	Yes	Yes	Yes	Yes
Building risk assessment	Yes	No	Yes	No
Identification of water system management points	Yes	Yes	Yes	No
Establishment of dead leg prevention plan	Yes	No	Yes	No
Monitoring of control measures and implementation of corrective actions	Yes	Yes	Yes	No
Validation that implemented control measures are inhibiting <i>Legionella</i> growth	Yes	Yes	Yes	Yes
Prevention plan completed for each building	No	Yes	Yes	No

Source: VA OIG analysis of all facility healthcare-associated Legionella disease prevention plans.

The audit team determined that the two facilities were able to maintain incomplete healthcare-associated *Legionella* disease prevention plans because VISN officials did not provide effective oversight and review processes for Directive 1061 compliance. Although the directive assigns responsibility for reviewing plan accuracy and completeness to the VA medical facility director, the VA medical facility water safety committee chair, and the VISN water safety liaison, it is the responsibility of the VISN to ensure that all VA medical facilities comply with VHA Directive 1061. In addition, the directive prescribes a required VISN review of facility healthcare-associated *Legionella* disease prevention plans for compliance. VISN officials were not able to provide the OIG with any documentation to certify compliance with the directive requirement that medical facility building healthcare-associated *Legionella* disease prevention plans were being reviewed and if any recommendations or updates occurred as a result.

The two facilities that established a dead leg prevention plan utilized an interagency agreement between the US Army Corps of Engineers and OHE for architect-engineer services to conduct a survey of their buildings to identify existing water systems and the location of any dead legs. The architect-engineer utilized by the Pittsburgh VA medical center used specialized scanning equipment to survey the facility's domestic water system, identify dead legs, and develop building information modeling.<sup>44</sup> As of July 2021, VISN 7, through the US Army Corps of

<sup>\*</sup> Facility used its single healthcare-associated Legionella disease prevention policy as both the required medical facility policy and prevention plan. VHA Directive 1061 requires facilities to have each; however, the OIG used the healthcare-associated Legionella disease prevention policy in its assessment in the absence of separate plans.

<sup>&</sup>lt;sup>44</sup> VA BIM STANDARD, *BIM Manual V2.2*, August 1, 2017. Building information modeling is a virtual representation of the physical and functional characteristics of a facility building that is used by VA to standardize building data available electronically. VA uses building information modeling to provide stakeholders with a greater understanding of how a building is to be planned, designed, constructed, used, operated, and managed.

Engineers, utilized an indefinite-delivery, indefinite-quantity contract to provide services to survey the existing domestic water system at the Dublin VA campus, and on August 31, 2022, executed a contract modification to add building information modeling. Building information modeling scanning efforts at the Dublin VA medical center were in process as of November 2022. The Brooklyn VA medical center's supervisory environmental engineer conveyed to the audit team that, as of January 2023, the facility has received fiscal year (FY) 2025 funding approval to obtain contracted services to conduct a building survey of its water system.

Recommendation 1 calls for the assistant under secretary for health for support to establish certification procedures for VISNs to ensure medical facilities' healthcare-associated *Legionella* disease prevention plans for buildings comply with VHA Directive 1061 requirements.

## None of the VA Medical Facilities Reviewed Consistently Followed Legionella Water Sampling Requirements

The audit team reviewed laboratory reports with test results for 2,201 *Legionella* water samples collected at the four facilities. For buildings under the purview of Directive 1061, the audit team evaluated whether samples collected met the quarterly testing requirements, including pure cold water sources and pure hot water sources. The audit team concluded that none of the four facilities adequately met the quarterly testing requirement for taking samples from an ice machine or other pure cold water source, with a cumulative total of 77.5 percent pure cold water outlets missing for all four quarters. Two of four facilities were also noncompliant with directive requirements for pure hot water sources, for a total of 12.5 percent missing for all quarters. Table 2 summarizes facility compliance for the required types of water samples collected.

Table 2. VHA Directive 1061 Water Sample Type Compliance

VA medical center	Missing quarterly tests for pure cold outlets	Required quarterly tests for pure cold outlets	Missed required pure cold tests	Missing quarterly tests for pure hot outlets	Required quarterly tests for pure hot outlets*	Missed required pure hot tests
Brooklyn	8	8	100%	0	8	0%
Dublin	8	8	100%	8	8	100%
Pittsburgh	13	32	40.6%	0	64	0%
Salem	64	72	88.9%	3	8	37.5%
Total	93	120	77.5%	11	88	12.5%

Source: VA OIG analysis of all facility water testing samples collected for FY 2021-Q3, FY 2021-Q4, FY 2022-Q1, and FY 2022-Q2. The OIG audit team verified that all buildings included in this analysis were under purview of VHA Directive 1061 and were active during the audit period.

\* VHA Directive 1061 states at least two of the 20 samples must be from a pure hot water source for each building tested, if such water outlets are available. Analysis considers availability of pure hot water outlets for the "Required quarterly tests for pure hot outlets" column.

The audit team also evaluated whether the water samples were first-draw samples as required by VHA Directive 1061. 45 The team reviewed laboratory reports with test results for the 2,201 water samples to confirm the total number of hot and cold water outlets tested. Based on review of facility water testing procedure documents and through verification of processes with facility staff, the OIG concluded that three of the four facilities did not comply with first-draw requirements for 475 sample tests (21.6 percent). All improperly drawn samples at these three facilities were done when conducting quarterly testing of pure hot water source samples for *Legionella*, where the audit team confirmed that individuals collecting the water samples ran the water until it reached a hot temperature prior to collecting the sample. Two of the three facilities communicated they were unsure of how to take a proper hot water sample from their outlets without letting the water run. The associate director with the VHA National Infectious Diseases Service confirmed that letting water run for at least 30 seconds would be considered flushing and is not in line with the directive for first-draw samples. The associate director further stated that it would be concerning if facilities flush water before testing, since evidence shows that flushing can give a false negative *Legionella* reading. 46

The audit team found that the medical facilities either did not take pure cold water or pure hot water test samples because medical facility staff either were unaware of the updated 2021 VHA directive requirements or did not realize that they did not complete all samples required. Additionally, two of the four facilities did not update their healthcare-associated *Legionella* disease prevention plans to include new water sampling procedures. The prevention plans at these two facilities still reflected rescinded 2014 VHA directive requirements of taking 10 cold and 10 hot samples, none of which were directed to be from a pure cold or pure hot water source. The directive published in February 2021 requires medical facilities to take 20 total samples, two of which must be from an ice machine or other pure cold water source, two from a pure hot water source, and the remainder as a first-draw sample from a source with a mixing valve at the outlet. The audit team determined that using outdated criteria could affect a

<sup>&</sup>lt;sup>45</sup> A first-draw sample is collected without flushing the tap first.

<sup>&</sup>lt;sup>46</sup> VHA Directive 1061 requires that, for quarterly *Legionella* water testing, at least two of the 20 water samples must be taken as the first draw from a pure hot water source of an outlet where no mixing valve is present, if available. If the facility does not have a pure hot water source is available, the remainder of the samples should be taken as mixed water samples by first draw.

<sup>&</sup>lt;sup>47</sup> VHA Directive 1061 requires medical facilities to review their healthcare-associated *Legionella* disease prevention plans at least once annually for accuracy and to update the plans as necessary to ensure they reflect current requirements.

<sup>&</sup>lt;sup>48</sup> VHA Directive 1061, *Prevention of Health Care-Associated Legionella Disease and Scald Injury from Potable Water Distribution Systems*, August 13, 2014.

<sup>&</sup>lt;sup>49</sup> Directive 1061 defines first-draw samples where a mixing valve is present as hot/cold "mixed" water samples.

facility's sampling, as a facility may not be drawing all required hot and cold samples or could be flushing mixed-valve outlets to draw hot samples for at least 10 samples to meet the previous 2014 directive requirement. These medical facilities' use of outdated requirements in their healthcare-associated *Legionella* disease prevention plans further demonstrates the need for improved VISN oversight and certification procedures.

The team determined that facilities were not in compliance with water collection sample requirements in part because medical facility and VISN leaders did not provide adequate oversight of the *Legionella* testing process. Although VHA Directive 1061 identifies which personnel at the facility are responsible for collecting the water samples and provides them with instructions on testing for *Legionella*, during the audit period, there was no action taken by VISN officials to ensure that medical facilities, when conducting or contracting for water testing services, were properly drawing all samples and/or including all required sample outlets.

Given facilities' inconsistent sampling, as well as not taking water samples at first draw for all required water samples, the audit team determined that VISN officials cannot confirm whether medical facilities are accurately testing in areas where *Legionella* proliferates, such as ice machines. Additionally, VISN officials further cannot confirm that facilities are drawing the most accurate mixed-valve samples if flushing is used to obtain hot samples.

VHA has created supplemental guidance regarding ice machines because they could encourage conditions conducive to *Legionella* growth if not properly maintained. Additionally, there have been past incidents identified outside of VA where Legionnaires' disease cases in hospitals have been linked to ice machines. If facilities do not include these or other pure cold outlets in routine water testing for *Legionella*, they can miss opportunities to identify potential sources of environmental exposure for patients, visitors, and staff. Similarly, as outlets may contain *Legionella* bacteria growth at the end section of a water system, such as in a faucet, flowing the water before drawing the water sample can flush *Legionella* out and give inaccurate test results. *Legionella* grows best within a temperature range of 77°F–113°F, so ensuring that water testing incorporates samples from hot water piping offers assurance that VA is assessing all water types that may be at risk of *Legionella* growth. Medical facilities may not identify and control areas of *Legionella* growth when they do not comply with testing procedures, increasing the risk for severe illness and death for individuals in the building.

Recommendation 2 calls for the assistant under secretary for health for support to ensure VISN officials perform and document quality control and quality assurance checks of VISN requirements for oversight and enforcement of the VHA Directive 1061 quarterly *Legionella* 

<sup>&</sup>lt;sup>50</sup> VHA Supplement 1061-2.2, "Ice Machines as a Source of Legionella and Other Opportunistic Premise Plumbing Pathogens," September 1, 2022.

<sup>&</sup>lt;sup>51</sup> Max A. Bencini MD, et al., "A Case of Legionnaires' Disease Caused by Aspiration of Ice Water," *Archives of Environmental and Occupational Health* 60, no. 6 (2005): 302–306, https://doi.org/10.3200/AEOH.60.6.302-306.

water testing procedures conducted by the facility. Recommendation 3 calls on the assistant under secretary for health for operations to monitor VISN officials to ensure fulfillment of their oversight responsibilities found in VHA Directive 1061 for *Legionella* water sampling, testing, remediation efforts, and reporting of *Legionella* water testing data, including the post-remediation test results.

## Three of the Four Facilities Did Not Fully Comply with Necessary Remediation Actions Required to Mitigate Potential *Legionella* Risk

The audit team reviewed laboratory reports for all four facilities during the audit period and determined that there was a total of 173 *Legionella*-positive samples at three of the facilities. The team found that two of the three facilities, the Salem and Brooklyn VA medical centers, accounting for 170 of the positive *Legionella pneumophila* samples, did not conduct all post-remediation testing after performing initial remediation efforts, as required by VHA Directive 1061. These facilities conducted 11.2 percent of their required post-remediation retesting.

Additionally, the Salem and Dublin VA medical centers did not repeat the remediation treatment and testing after *Legionella* levels remained at or above 1 CFU/ml, including one facility with remaining elevated *Legionella pneumophila* species levels.<sup>53</sup>

Table 3 reflects a summary of post-remediation testing that was performed according to VHA Directive 1061 requirements for the two medical facilities that did not conduct all their required post-remediation retesting.

Table 3. VHA	Directive 1061	Post-Remediation	Testing (	Compliance

Medical facility	Post-remediation tests performed	Quarterly positive samples (=>1 CFU/ml)	Percentage of post-remediation tests performed
Salem	6	144	4.2%
Brooklyn	13	26	50%
Total	19	170	11.2%

Source: VA OIG analysis of FY2021 Q3–FY2022 Q2 reported WSMT positive Legionella pneumophila routine test results, laboratory reports of Legionella sample results, and facility remediation action completion support documentation.

The audit team determined that contributing to the inadequate post-remediation testing at two of the facilities was lack of clarity in the directive responsibilities section regarding remediation completion, including the post-remediation follow-up testing. The audit team spoke with the

<sup>&</sup>lt;sup>52</sup> For the purposes of this report, the term "positive" means water samples showing *Legionella* bacteria at a concentration of one colony-forming unit per milliliter (CFU/ml) or greater.

<sup>&</sup>lt;sup>53</sup> Repeated remediation treatment and water testing are required when *Legionella pneumophila* species are still present at a concentration at or above 1 CFU/ml after prior remediation efforts.

senior area manager for the contracted company that performed water testing for the Brooklyn VA medical center to determine why post-remediation testing did not occur for the first quarter of FY 2022. The senior area manager could not confirm a reason why it was not initially conducted but noted a lack of communication from the facility regarding coordinating for the contractor to return for post-remediation testing.

VHA Directive 1061 requires that remediation and retesting requirements be repeated on all areas that tested positive until efforts are successful at reducing levels of *Legionella* positivity. Once the *Legionella* is reduced in accordance with requirements in the directive, then the quarterly testing cycle is complete. Reporting *Legionella* test results is required for all water samples taken in accordance with the directive, including routine and post-remediation testing. The audit team reviewed all incidents at the four medical facilities where retesting results after initial remediation showed remaining positive *Legionella* samples. The audit team found that two of the facilities took no action to repeat remediation treatment as required when post-remediation test results demonstrated that *Legionella pneumophila* levels remained at or above 1 CFU/ml. Example 1 describes repeated remediation when an elevated *Legionella* level was detected after initial efforts.

### Example 1

The Dublin VA medical center had three outlets that tested positive for Legionella pneumophila at or above 1 CFU/ml in its routine quarterly testing results on June 17, 2021. The facility performed thermal eradication on June 30, 2021, and retested the areas of positivity on July 6, 2021. After remediation, one of the three outlets still showed elevated Legionella levels. The audit team confirmed with the facility's environmental protection specialist that the facility did not repeat the remediation efforts on the remaining positive outlet and instead decided to test it the next quarter. This is not in compliance with directive requirements to repeat remediation and testing until efforts are successful at reducing levels of Legionella positivity.

## One Facility Has Continued to Face Persistent *Legionella* despite Efforts to Comply with Directive Requirements

The Salem VA medical center experienced persistent positive *Legionella* water testing results despite demonstrated efforts to comply with VA Directive 1061 remediation and mitigation requirements, including previously implementing all of the minimum remediation actions required to mitigate potential *Legionella* risk. The facility has reported approximately a 53 percent rate of any occurrence of *Legionella* bacteria in its water samples in nine of its buildings over the past seven years. This has occurred despite the facility conducting hyperchlorination and thermal remediation efforts to mitigate potential *Legionella* risk, and

utilizing point-of-use filters and routine flushing of hot and cold water at outlets in attempt to access or prevent *Legionella* growth in building water distribution systems. The chief of Facility Management Services (FMS) explained that during the audit period, the facility decided to discontinue remediation efforts for two quarters, and, for the remaining two quarters, conduct limited remediation, despite positive test results greater than 1 CFU/ml. Despite these environmental *Legionella* testing results, records from the Inpatient Evaluation Center data management system reflected that no healthcare-associated Legionnaires' disease cases were identified or reported for the Salem VA medical center during the audit period.<sup>54</sup>

The chief of Facility Management Services stated past efforts using thermal eradication led to unsustained results at the facility, including incidents of higher levels of growth shortly after remedial actions. The facility director further stated that past hyperchlorination remediation efforts have been labor-intensive, and improvements of Legionella bacteria levels detected in the facility water supply have typically only lasted about 30 days on average before they begin to rise again. In addition to conducting remediation efforts required by VHA Directive 1061, the facility identified existing dead legs in its building prevention plan that are likely also contributing to Legionella growth and persistence. As referred to earlier, the directive also requires medical facility healthcare-associated Legionella disease prevention plans to identify existing dead legs, assess their risk for contributing to Legionella growth, and create a schedule to remove them. However, the chief of FMS has conveyed that the facility has not been able to successfully secure a contractor to remove these dead legs and has created statements of work in multiple attempts to contract for this work. In January 2023, the chief of FMS stated that the difficulty in obtaining a contractor for this work is due to limited bids that have pricing higher than available funds. This has resulted in the facility discontinuing its pursuit of contractors to remove dead legs until leaders are able to mitigate the excessive pricing.

In February 2019, the medical facility was approved for approximately \$3.5 million to renovate its water supply system to provide chlorine residual throughout the facility and address its persistent *Legionella* issue.<sup>55</sup> This funding was specific to adding proper chlorination distribution throughout the facility water system through building renovations, modifications to piping and chemical feed pumps and equipment, electrical and heating, ventilation, and air conditioning (HVAC) improvements, and the addition of remote water quality monitoring. Removal of dead leg piping was not included in the scope of work for this project. The contract was awarded on

<sup>&</sup>lt;sup>54</sup> The Inpatient Evaluation Center (IPEC) is the official repository for *Legionella* clinical information and *Legionella* case report data. The IPEC data management system is an internal VA website, not available for public viewing, which contains facility-reported data on infections.

<sup>&</sup>lt;sup>55</sup> CDC Safe Water System Project, "Chlorine Residual Testing Fact Sheet," accessed May 2, 2023, <a href="https://www.cdc.gov/safewater/publications\_pages/chlorineresidual.pdf">https://www.cdc.gov/safewater/publications\_pages/chlorineresidual.pdf</a>. The presence of chlorine residual in drinking water indicates that (1) a sufficient amount of chlorine was added initially to the water to inactivate the bacteria and some viruses that cause diarrheal disease and (2) the water is protected from recontamination during storage.

August 29, 2019, and the certification of substantial work completion was signed by the contractor in February 2021. As of March 2023, the Salem VA medical center continued to study and adjust the parameters of the system to maintain the output in a safe range before full integration. Despite having knowledge of the impending addition of the chlorine residual project, the facility staff expressed frustration regarding the current remediation options within VHA Directive 1061 and described to the audit team the need for additional expertise in finding new methods to control *Legionella* growth.

The audit team's review identified one medical facility that successfully mitigated persistent *Legionella* and probed the reasons for its success. From April 1, 2021, through March 31, 2022, the Pittsburgh VA medical center had zero water samples test positive for *Legionella pneumophila*. Unlike the other medical facilities the audit team examined, this facility had its own on-site laboratory that was certified by the CDC to perform *Legionella* testing, and also operated as a permitted water treatment authority with licensed operators on staff. It also had facility experts in microbiology, infection prevention, infectious diseases clinical service, and water safety to address concerns with *Legionella* or other waterborne bacteria.

Recommendations 4 and 5 are directed to the director of OHE. Recommendation 4 calls on OHE to consider alternative measures, such as adding dedicated resources, to provide expertise and support for medical facilities experiencing persistent positive *Legionella* in facility water supply systems after applying the remediation efforts prescribed by VHA Directive 1061. Recommendation 5 calls for assisting the Salem VA medical center with persistent *Legionella* in the facility water supply system, and, with consideration of the ongoing water supply system renovations, develop an action plan to mitigate remediation challenges.

# Improved Communication to Oversight Officials Is Needed When Facility Staff Have Difficulty Conducting Required Remediation Actions

The audit team reviewed all positive *Legionella* water testing samples and associated remediation actions conducted for the four facilities reviewed and found lapses in communication regarding remedial actions with officials responsible for conducting oversight and consultation. For example, the Salem medical center, which faced persistent positive *Legionella* water samples, did not conduct any remediation for 133 of 144 positive *Legionella pneumophila* quarterly testing samples (about 92 percent) during the audit period. Salem's chief of Facility Management Services reiterated to the audit team that the facility's past experiences with remediation actions prescribed by VHA Directive 1061 had only resulted in minimal success lowering or eradicating *Legionella*.

The audit team also spoke with the director of OHE regarding his awareness of the reoccurring positive *Legionella* test results at the Salem VA medical center and the facility not following VHA remediation protocols. The OHE director was unaware that the Salem VA medical center

was experiencing persistent *Legionella* problems and that it discontinued remediation efforts during the audit period. According to the director, facilities are expected to continue remediation efforts whenever they have a positive *Legionella* sample detected in quarterly testing results. When facilities have discontinued or faced challenges with remedial efforts, OHE first expects the facility to raise these issues with the VISN water safety liaison, followed by notification through issue briefs or other direct communication from the VISN to trigger OHE's involvement. Directive 1061 instructs the VISN water safety liaison to coordinate communication between VHA's central office and VISN or VA medical facility staff regarding water safety and *Legionella* prevention actions, policies, guidance, or events. However, the audit team did not find any specific language in VHA Directive 1061 that conveyed expectations for communication through issue briefs or the requirement for VISN officials to communicate challenges specific to remediation at all management levels. Despite that lack of specificity, example 2 describes how a facility successfully coordinated with OHE to alter its remediation practices.

### Example 2

The Pittsburgh VA medical facility experienced a Legionella outbreak in 2012. To remediate persistent Legionella levels that led to patients being infected with Legionnaires' disease, the facility frequently hyperchlorinated its water systems on both campuses from approximately 2012 to 2014, using levels at or above 20-50 parts per million (ppm) of chlorine. This practice was consistent with the first VHA Legionella directive, published in February 2008. 56 According to a plumbing shop supervisor and water treatment plant operator, the medical facility's plumbing system was damaged in part due to the facility's extended hyperchlorination efforts. The former chief of Facility Management Services stated that OHE visited the Pittsburgh VA medical facility several times between 2012 and 2014 to learn and communicate with the facility about their remediation process experiences. The director of OHE and the associate director of the VHA National Infectious Diseases Service shared how their experiences working with the facility, along with guidance published from entities such as the CDC and the American Society of Heating, Refrigerating and Air-Conditioning Engineers, factored into decisions to lower the recommended chlorine levels in remediation protocols.<sup>57</sup> The collaboration between the facility and OHE also reinforced the importance of communication through an on-site team and, as a result, contributed to the directive's facility water safety committee requirement.

<sup>&</sup>lt;sup>56</sup> VHA Directive 2008-010, *Prevention of Legionella Disease*, February 11, 2008.

<sup>&</sup>lt;sup>57</sup> The American Society of Heating, Refrigerating and Air-Conditioning Engineers is an industry resource for standards, research, publications, and educational materials relating to total building design, energy efficiency efforts, and sustainable building technologies.

Per VHA Directive 1061, OHE is available to consult with VISNs and medical facilities for guidance on remediation, and the director of OHE is responsible for providing consultative assistance related to engineering requirements to VISNs and VA medical facilities as needed. Requests for consultative assistance related to *Legionella* prevention efforts from OHE, VHA's National Infectious Diseases Service, or the water safety liaison fall under the responsibility of the facility medical director. Further, it is the responsibility of the VISN director to inform leadership when barriers to VA medical facility compliance with the directive are identified. Therefore, it is incumbent on facility and VISN officials to collaborate and communicate any challenges faced when complying with required remediation practices.

Recommendation 6 calls on the director of OHE to clarify VHA Directive 1061's responsibility section to clearly define oversight responsibilities for ensuring required remediation steps are completed when facilities receive positive *Legionella* water test results.

## None of the VA Medical Facilities Reviewed Consistently Reported Legionella Test Results to the VHA Water Safety Management Tool

The audit team determined that none of the four VA medical facilities reviewed consistently reported *Legionella* water test results to VHA leaders and VISN officials. VHA officials rely on medical facilities to report quarterly and post-remediation testing data to the WSMT for oversight of facility engineering controls and to identify facilities with potential data inconsistencies so they can address areas of concern. This information is also important for facility engineering to determine whether controls in place are working effectively or if new strategies or technology needs to be employed. In addition, during the audit period, OHE and VHA National Infectious Diseases Service developed an automated trend analysis tool of routine quarterly environmental sampling results entered into the WSMT to aid VISNs and facilities in analyzing and visualizing engineering control effectiveness. According to VHA officials, WSMT data was being utilized in the development phase of this tool to validate trend report outputs. This trend analysis tool was implemented in April 2023, after the audit team reviewed reported *Legionella* water test results.

VHA Directive 1061 requires medical facility directors to report all *Legionella* test results, including routine testing and post-remediation testing, to the VHA WSMT database. The VISN water safety liaison must then analyze and validate the WSMT *Legionella* testing data to confirm VA medical facility compliance with reporting requirements.<sup>58</sup> The director of OHE stated that he relies on the VISN water safety liaison to ensure compliance with the directive due to limited resources in his office for monitoring *Legionella* test data.

<sup>&</sup>lt;sup>58</sup> VHA Directive 1061, *Prevention of Health Care-Associated* Legionella *Disease and Scald Injury from Water Systems*, February 16, 2021.

To determine if routine quarterly testing was recorded in accordance with the directive, the audit team reviewed all WSMT data entries during the audit period for the four medical facilities reviewed. The audit team compared all WSMT *Legionella* water test result data as of October 12, 2022, to the corresponding water sample reports from the testing laboratories for the same time frame.<sup>59</sup> Table 4 reflects a summary of the four medical facilities that did not report all required quarterly routine water testing and post-remediation test results in the WSMT for the four quarters in the sample.

Table 4. VHA Directive 1061 Noncompliance with Reporting
Test Results in WSMT

Facility	Missing reported routine tests in WSMT	Total tests conducted	Missing routine testing results in the WSMT	Missing tests post- remediation	Missing post- remediation testing results in WSMT
Salem	180	720	25%	31	100%
Brooklyn	26	114	23%	16	100%
Pittsburgh	181	1,183	15%	0	0%
Dublin	184	184	100%	3	100%

Source: VA OIG analysis of FY2021 Q3–FY2022 Q2 water test results reported in the WSMT, and all facility water testing samples collected from either third-party laboratory reports or VA medical center laboratory databases for FY 2021-Q3, FY 2021-Q4, FY 2022-Q1, and FY 2022-Q2.

Example 3 shows a facility that did not report any routine testing or post-remediation results in the WSMT for all the quarters in this audit period because the VISN water safety liaison did not follow data-reporting requirements.

## Example 3

The Dublin VA medical center used a contractor to perform Legionella water testing at its facility. The contractor conducted a total of 184 Legionella water sample tests during the audit period, but the facility did not enter any of the test results into the WSMT to make the data accessible to oversight officials. The three test results the audit team found for this time were tests performed in earlier quarters, and the data was inaccurate. The VISN 7 occupational safety and health

<sup>&</sup>lt;sup>59</sup> VHA Directive 1061 requires all testing laboratories be accredited by a recognized regional, national, or international accrediting body in accordance with a laboratory accreditation standard, such as the National Environmental Laboratory Accreditation Program (NELAP), the American Association for Laboratory Accreditation (A2LA), or the Environmental Microbiology Laboratory Accreditation Program (EMLAP). Further, laboratories must demonstrate proficiency by the 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.

manager stated that the Dublin VA medical center environmental protection specialist encountered difficulty loading water test results into the WMST. As a result, the prior VISN water safety liaison had allowed the facility to submit test results in the form of an Excel spreadsheet instead of entering data into the WSMT. This process circumvented the data-reporting requirement. The current VISN water safety liaison and the VISN 7 occupational safety and health manager both confirmed that they were unaware the prior water safety liaison was allowing this to occur. The VISN water safety liaison acknowledged that, as part of his role, he is responsible for overseeing data and ensuring it is entered into the WSMT. The liaison confirmed that upon taking over the role in 2022, training was provided to the facility staff to correct this process and ensure that data are uploaded into the WSMT.

The audit team further determined that a lack of oversight and Legionella testing data validation by the VISN water safety liaison could potentially result in critical data not being accessible in the WSMT to VISN and VHA oversight officials. According to the WSMT user guide, medical facilities are required to input all Legionella test results within one week of receiving them, followed by allotting the VISN 45 days from the end of the quarter to certify and lock the data.<sup>60</sup> The audit team initially extracted *Legionella* testing result data from the WMST for the audit period on June 13, 2022, and found that one of the reviewed facilities, the Salem VA medical center, was missing three quarters of Legionella test results despite required deadlines for data reporting having passed. However, after the OIG provided notification of an intended site visit, the facility input two quarters of the missing data on September 1, 2021, past the required time frames for inputting the data and not in compliance with policy frequency. The chief of Facility Management Services explained that the remaining missing quarter of Legionella test results was not entered due to a bid protest for the awarded Legionella water testing contract. If timely testing data are unavailable, VA leaders lack awareness of Legionella conditions in individual medical facilities and will not be able to effectively monitor safety concerns and respond appropriately. Example 4 provides details of the two quarters of missing routine data in the WSMT and the delay in reporting for this facility.

## Example 4

The Salem VA medical center missed its data-reporting deadlines by seven months and four months in two different quarters. Both data sets were not reported until September 1, 2022, notably after the OIG notified the facility of an upcoming site visit. Despite receiving several automated email alerts for data that were missing from the WSMT system by the required entry deadlines of

<sup>&</sup>lt;sup>60</sup> VHA, Water Safety Management Tool User Guide, October 2021.

February 11, 2022, and May 13, 2022, the VISN water safety liaison confirmed that he did not follow up with the facility on the missing data. Facility staff also confirmed that they did not receive notifications or reminders from the VISN water safety liaison or OHE alerting them of missing data or that they had missed deadlines for entry. The test results for these two quarters indicated the facility had 76 positive Legionella pneumophila samples at a concentration of 1 CFU/ml or greater and had a total of 216 positive Legionella samples overall. However, these positive results were unreported by the facility in the WSMT until significantly past data entry deadlines and were therefore not available for analysis until a delayed date.

The audit team determined that the VISN water safety liaisons for three of the four sampled medical facilities did not provide adequate oversight of VA medical facility directors to ensure compliance with *Legionella* test result reporting requirements, including frequency and time frame. Moreover, although facilities are required to input positive results for routine *Legionella* testing in the WSMT, no controls were in place at the VISN level to track those results for future monitoring to confirm post-remediation testing was completed and recorded as required.

Recommendation 7 calls on the director of OHE to modify the WSMT to alert VISN and medical facility oversight officials when quarterly testing data are not posted.

## Medical Facility Staff Were Not Properly Notified When Positive Legionella Levels Were Detected in Three Medical Facilities

The audit team found that two of the four VA medical facilities did not communicate any of the positive *Legionella* test results to clinical staff during the audit period, for a total of 398 positive water testing samples. Additionally, the OIG found that one of the four medical facilities would alert clinical staff only when water test results were positive for *Legionella pneumophila* serogroup 1, which did not meet the VHA Directive 1061 requirement for the notification to include positive samples for all *Legionella* species and serogroups. According to the CDC, most species and serogroups of *Legionella* are potentially harmful; therefore, communicating all positive *Legionella* results is imperative for proper clinical response. As a result of reporting only one serogroup, this medical facility missed communicating a total of 38 positive *Legionella* water testing results during the audit period that should have been brought to the attention of front-line clinical staff.

The reviewed medical facilities lacked compliance with the directive communication requirements for positive *Legionella* test results detected in routine water samples in part due to a lack of adequate oversight by the VISN director to ensure the facility chief of staff and associate

<sup>&</sup>lt;sup>61</sup> "Legionella Disease Specifics—Disease Specifics" (web page), CDC, accessed March 9, 2023, <a href="https://www.cdc.gov/legionella/clinicians/disease-specifics.html">https://www.cdc.gov/legionella/clinicians/disease-specifics.html</a>.

director of patient care services communicated positive *Legionella* results to clinical staff as required to initiate diagnostic awareness for clinical testing. VHA Directive 1061 states that the VISN director is responsible for ensuring that all VA medical facilities within the VISN comply with the directive for prevention of Legionnaires' disease, including reporting requirements for clinical and environmental testing.

Legionella test results were communicated at quarterly water safety committee and infection control meetings, which comprised members from different clinical areas. However, the three facilities reviewed were not able to obtain evidence that this information was broadly distributed to clinical staff involved with direct patient care, as required by VHA Directive 1061.<sup>62</sup>

Despite the initial lack of notification processes to alert front-line clinicians of positive *Legionella* test results, the audit team found that some facilities had taken proactive steps to begin communicating all positive results received during the quarterly water testing cycle. While the audit team was on-site, two medical facilities provided documentation that they have since updated their communication processes to begin disseminating results, with one facility beginning regularly planned notification practices in September 2022 and the other beginning in November 2022.

According to the CDC, there is no known safe level or type of *Legionella* in water systems.<sup>63</sup> Therefore, the presence of any detected *Legionella* in routine water samples should trigger response activities. Communicating their presence to clinicians involved in direct patient care is critical to ensuring that clinicians perform appropriate antigen testing for Legionnaires' disease that could potentially be contracted within medical facilities.<sup>64</sup>

Recommendation 8 calls on the assistant under secretary for health for operations to take actions to confirm that VISN officials are ensuring front-line staff are routinely notified by responsible medical facility officials when elevated *Legionella* water sample levels require diagnostic awareness and additional clinical surveillance of veterans to detect Legionnaires' disease.

#### Conclusion

VHA needs increased assurance that medical facilities are consistently identifying, mitigating, reporting, and communicating *Legionella* found in water systems in VA-owned buildings in which patients, residents, employees, or visitors stay overnight. Incomplete healthcare-associated *Legionella* disease prevention plans, lack of alternative measures to resolve persistent *Legionella* 

 $<sup>^{62}</sup>$  The OIG assessed communication of test results but did not incorporate evaluation of clinical actions taken as a result of *Legionella* detection into this audit.

<sup>&</sup>lt;sup>63</sup> "Legionella—Monitoring Your Building Water" (web page), CDC, accessed March 29, 2023, https://www.cdc.gov/legionella/wmp/monitor-water.html.

<sup>&</sup>lt;sup>64</sup> Directive 1061 requires clinicians to use both urinary antigen testing and sputum culture for diagnosis of Legionnaires' disease when the *Legionella* detected is *Legionella pneumophila* serogroup 1. For positive *Legionella* species other than *Legionella pneumophila* serogroup 1, use of sputum culture only is appropriate.

despite demonstrated efforts to comply with VHA Directive 1061 remediation and mitigation requirements, improper water sampling, unreported testing data, and lack of consistent actions to remediate and communicate *Legionella* levels affect oversight of *Legionella* conditions in individual medical facilities. These issues also have the potential to delay clinical staff diagnostic approaches for vulnerable patients. By addressing these issues and continuing to improve and enforce *Legionella* prevention and control practices at VA medical facilities, VA can reduce the risk of healthcare-associated Legionnaires' disease for veterans and employees.

#### Recommendations 1-8

- 1. The assistant under secretary for health for support should establish certification procedures for Veterans Integrated Service Networks to ensure medical facilities' healthcare-associated *Legionella* disease prevention plans for buildings comply with Veterans Health Administration Directive 1061 requirements.
- 2. The assistant under secretary for health for support should develop and ensure Veterans Integrated Service Networks perform and document quality control and quality assurance checks of their requirements for oversight and enforcement of the Veterans Health Administration Directive 1061 quarterly *Legionella* water testing procedures conducted by the facility.
- 3. The assistant under secretary for health for operations should monitor Veterans Integrated Service Network officials fulfillment of their oversight responsibilities found in Veterans Health Administration Directive 1061 regarding *Legionella* water sampling, testing, remediation efforts, and reporting of *Legionella* water testing data, including the post-remediation test results.
- 4. The director of the Office of Healthcare Engineering should consider alternative measures, such as adding dedicated resources, to provide expertise and support for medical facilities experiencing persistent positive *Legionella* in facility water supply systems after applying the remediation efforts prescribed by Veterans Health Administration Directive 1061.
- 5. The director of the Office of Healthcare Engineering should assist the Salem VA medical center with their persistent positive *Legionella* in the facility water supply system, and, with consideration of the ongoing water supply system renovations, develop an action plan to mitigate remediation challenges.
- 6. The director of the Office of Healthcare Engineering should clarify the responsibility section of Veterans Health Administration Directive 1061 to clearly define oversight responsibilities for ensuring required remediation steps are completed when facilities received positive *Legionella* water test results.

- 7. The director of the Office of Healthcare Engineering should revise the Water Safety Management Tool to alert Veterans Integrated Service Network and medical facility oversight officials when quarterly testing data is not posted.
- 8. The assistant under secretary for health for operations should take actions to confirm that Veterans Integrated Service Network officials are ensuring front-line staff are routinely notified by responsible medical facility officials when elevated *Legionella* water sample levels require diagnostic awareness and additional clinical surveillance of veterans to detect Legionnaires' disease.

## **VA Management Comments**

The under secretary for health concurred or concurred in principle with all eight recommendations and submitted an action plan for each. In response to recommendations 1, 2, 3, and 8, VHA will institute certification processes to confirm that medical facilities comply with the requirements in the directive; VISNs perform quality control checks on their completion of required oversight and review processes for facility quarterly *Legionella* water testing; VISNs oversee *Legionella* water sampling, testing, remediation efforts and reporting of *Legionella* water testing data, including the post-remediation test results at medical facilities; and front-line staff are being notified of elevated *Legionella* water sample levels, as required by the directive.

In response to recommendation 4, the director of OHE will evaluate the ability to add dedicated staff to provide support and oversight of the national water safety program, including providing expertise and support for medical facilities experiencing persistent positive *Legionella* in facility water supply systems after applying the remediation efforts prescribed in the directive. The director of OHE will also work with VISN 6 to support the Salem VA medical center in evaluating their engineering controls and remediation processes for the management of *Legionella* in their system, which addresses recommendation 5. Finally, in response to recommendations 6 and 7, the OHE director will update the language in the directive's responsibilities section to further clarify that the oversight responsibilities for the VA medical facility water safety committee chair include ensuring required remediation steps are completed when facilities received positive *Legionella* water test results, as well as update the WSMT to include an alert function to notify VISN and medical facility oversight officials when quarterly water testing data are not posted.

All action plans are targeted for completion by December 2023. Appendix C provides the full text of the under secretary for health's comments and planned actions.

## **OIG Response**

The under secretary for health's comments and planned corrective actions are responsive to the intent of the recommendations. The OIG will monitor execution of planned actions and will

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close the recommendations when VHA provides sufficient evidence demonstrating progress addressing the issues identified.

## Appendix A: Background

## Legionella Water Testing Outside VA

Federal law and regulations, including the Safe Drinking Water Act, do not explicitly address *Legionella* in water systems. The Centers for Disease Control and Prevention (CDC) has provided a framework of guidelines to provide resources for those who choose to address reducing *Legionella* risk in occupational and healthcare settings. However, in the absence of a federal law that targets *Legionella* contamination of water supplies or provides substantial control of *Legionella* in water systems, identifying how much *Legionella* routine water testing is occurring outside VA is very difficult.

## **History of VHA Directive 1061**

Prior to a VA Office of Inspector General (OIG) June 2007 report, Assessment of "Legionnaire's Disease Risk in Veterans Health Administration Inpatient Facilities, the Veterans Health Administration (VHA) did not require medical facilities to have a written plan in place to address the prevention of Legionnaires' disease at inpatient facilities where bone marrow and solid organ transplants are performed, or require these facilities to conduct periodic assessment of local risk of Legionnaire's disease. 66 The OIG recommended that the under secretary for health take the required actions to ensure that inpatient facilities where transplants are performed have a written plan that addresses the prevention of Legionnaires' disease, and that all inpatient facilities periodically assess local risk for Legionnaires' disease using specific guidelines developed by VHA experts. VA concurred with the recommendations, and in February 2008, VHA implemented Directive 2008-010, for the prevention of healthcare-associated Legionnaires' disease at VHA inpatient facilities. Since this directive, there have been two iterations of VHA Directive 1061, Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems. The first, published in 2014, was rescinded, and the most recent, dated February 16, 2021, is still in effect. The major changes from the 2014 to the 2021 directive were to expand and clarify its scope and applicability, add provisions on non-potable water (cooling towers), and update provisions on Legionella testing and actions for potable water systems. The directive primarily addresses the prevention of Legionnaires' disease and scald injury from water systems in VHA buildings in which patients, residents, or visitors stay overnight. It does so by focusing on Legionella management through the assessment of risk, monitoring water quality, implementing engineering controls, and validating that the control measures are effective at

<sup>&</sup>lt;sup>65</sup> "Legionella—Guidelines, Standards, and Laws" (web page), CDC, accessed March 8, 2023, https://www.cdc.gov/legionella/resources/guidelines.html.

<sup>&</sup>lt;sup>66</sup> VA OIG, Assessment of Legionnaire's Disease Risk in Veterans Health Administration Inpatient Facilities, Report No. 07-00029-151, June 20, 2007.

inhibiting *Legionella* growth. The directive was amended on September 26, 2022, but did not include changes that affected the scope of this audit.

The assistant under secretary for health for support is responsible for the contents of the directive. Meanwhile, the Office of Healthcare Engineering (OHE) is responsible for responding to questions regarding the engineering aspects of this directive. Additionally, OHE is responsible for developing supplemental guidance such as engineering requirements, standards, or guidelines. OHE and VHA National Infectious Diseases Service have developed various guidance documents and supplements for Legionella, including Routine Environmental Sampling of Building Potable Water Systems for Legionella and Other Parameters in Water, Risk Assessment for Prevention of Healthcare-associated Infections caused by Legionella and Other Water-related Pathogens, Exporting Data from the Water Safety Management Tool and General Guidance for Data Analysis, and Ice Machines as a Source of Legionella and Other Opportunistic Premise Plumbing Pathogens.

## VHA Directive 1061 Roles and Responsibilities

The **assistant under secretary for health for operations** is responsible for communicating the contents of the directive to each of the VISNs; assisting VISN directors with resolving implementation and compliance challenges in all VA medical facilities within that VISN; and providing oversight of VISNs to ensure compliance with the directive, relevant standards, and applicable regulations.

The VHA Office of Healthcare Engineering (OHE) is a subordinate organization under Healthcare Environment and Facilities Programs. The director of OHE is responsible for the engineering aspects of the directive, including assessing the implementation program for currency and effectiveness and developing and issuing any additional engineering requirements, standards, and guidelines for the prevention of Legionnaires' disease. The OHE director is also responsible for providing as-needed consultative assistance for the engineering requirements to VISNs and VA medical facilities, as well as administering the WSMT for the collection of *Legionella* data to facilitate analysis and action.<sup>67</sup>

The **director of the National Infectious Diseases Service** is responsible for developing procedures and guidelines within VHA for *Legionella* prevention in combination with other VHA program offices, as necessary. The director of National Infectious Diseases service is also responsible for managing and reviewing the centralized collection of Legionnaires' disease case data from VA medical facilities, as well as providing consultative assistance to VISNs and VA medical facilities related to the risk and clinical aspects of Legionnaires' disease and validation requirements.

<sup>&</sup>lt;sup>67</sup> The VHA Water Safety Management Tool (WSMT) is an internal VA website used as a repository to report and document water sampling of VHA-owned buildings.

The **VISN** directors are responsible for ensuring that all VA medical facilities within the VISN comply with the directive and that annual healthcare-associated *Legionella* disease prevention plans are completed, including annual recertification, reporting requirements, and clinical and water testing.

The **VISN water safety liaison** is responsible for obtaining and reviewing annual healthcare-associated *Legionella* prevention plans, reports, and clinical and water testing from all VA medical facilities within the VISN. The VISN water safety liaison also coordinates 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, and develops VISN-level policies and procedures related to healthcare-associated Legionnaires' disease prevention. The VISN water safety liaison is also responsible for reviewing and validating WSMT data, and well as consulting with VA medical facilities to improve performance.

The VA medical facility director is responsible for establishing a VA medical facility Legionnaires' disease prevention policy in alignment with VHA Directive 1061 and ensuring that each building has a written prevention plan. Additionally, the director's responsibilities include approving these plans and guaranteeing actions are implemented. The director should also ensure that all water testing for *Legionella* is conducted in accordance with the directive, and that the quarterly and post-remediation test results are submitted to the WSMT.

The VA medical center chief of engineering is responsible for ensuring the VA medical facility has a plan for removing unused potable water branch lines and dead legs, as well as capping at the main supply or recirculation supply lines to limit stagnation and the potential for *Legionella* growth.

The **facility water safety committee chair** is responsible for conducting an annual assessment to determine which buildings are subject to VHA Directive 1061 and developing and reviewing written healthcare-associated *Legionella* prevention plans at least annually for those buildings. This role is also responsible for establishing the plan for conducting water testing for *Legionella*, determining the number and location of water samples to be tested, recommending a laboratory to process the water samples, and conducting routine committee meetings at least quarterly to discuss water testing results. Additionally, the chair is responsible for conducting routine committee meetings at least quarterly to review building-associated risks, documenting verification of directive implementation, discussing findings and remedial actions from positive tests, and any corrective actions for engineering controls.

The **facility water safety committee** is responsible for determining what remedial actions, if any, will be implemented in occurrences where the *Legionella* species detected was not *pneumophila*, or was *pneumophila* at less than one colony-forming unit per milliliter (CFU/ml). Additionally, if there are water samples that tested positive in different areas of the building or on different water distribution loops, the 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.

The VA medical facility chief of staff and VA medical facility associate director of patient care services are responsible for collaborating to ensure that clinical staff involved in direct patient care are notified in a timely manner when routine water testing is positive for *Legionella*, to increase diagnostic awareness.

## Previous Legionella at VA Facilities

There have been past occasions of *Legionella* contamination or cases of disease spreading in VA facilities. Below are some examples:

- Legionella was discovered at the Loma Linda VA Medical Center, putting patients and staff at risk. VA officials failed to notify physicians in 2017 about Legionella bacteria, posing a public health danger and possibly causing at least one doctor to contract severe Legionnaires' disease, according to an internal 2018 VA Office of the Medical Inspector report. The report also substantiated a whistleblower complaint, received by the US Office of Special Counsel by two doctors and six nurses at the Loma Linda facility, that alleged hospital officials failed to notify staff and correct elevated levels of Legionella that had been detected in the facility's water system for months.<sup>68</sup>
- The VA OIG conducted a healthcare inspection at the Loma Linda VA Medical Center and published a report in June 2019 with relevant recommendations ranging from policy practices to implementing standardized processes to inhibit *Legionella* growth. 69
- A Legionnaires' disease outbreak at the VA Pittsburgh Healthcare System in 2012 resulted from inadequate monitoring of the water management program. At least 22 patients were sickened by this outbreak and five died. A CDC report found that Pittsburgh VA medical center drinking water had widespread colonization of *Legionella* and described it as a failure to recognize cases of *Legionella* for an extended period of time.<sup>70</sup>

<sup>&</sup>lt;sup>68</sup> VHA Office of the Medical Inspector, Report to the Office of Special Counsel, *Department of Veterans Affairs Loma Linda VA Medical Center*, Report No. TRIM 2018-D-3356, October 9, 2018 (this report is not publicly accessible).

<sup>&</sup>lt;sup>69</sup> VA OIG, <u>Review of Environment of Care, Infection Control Practices, Provider Availability, and Leadership at the VA Loma Linda Healthcare System, California</u>, Report No. 18-02405-146, June 18, 2019.

<sup>&</sup>lt;sup>70</sup> "The CDC investigation of Legionnaires' disease among patients at the VA Pittsburgh Healthcare System," CDC, accessed April 25, 2023, https://www.cdc.gov/washington/testimony/2018/t20130205.html (later archived and found at https://archive.cdc.gov/#/details?url=https://www.cdc.gov/washington/testimony/2013/t20130205.html).

#### **CDC Guidelines**

The CDC defines a *Legionella* outbreak as two or more cases of confirmed Legionnaires' disease occurring in one location.<sup>71</sup> The CDC is only involved in outbreak investigations when a health department requests additional assistance. According to VHA supplemental guidance for *Legionella* published in June 2022, about 10,000 cases of Legionnaires' disease were reported in the United States in 2018.<sup>72</sup> The actual number of cases is likely higher due to underdiagnosis. Cases are increasing throughout the United States; in addition, the supplemental guidance cited a CDC study that estimated the true number of Legionnaires' disease cases may be 1.8–2.7 times higher than what is reported.

The CDC provides performance indicators as guidelines for potable water:

- If ≤1 colony-forming unit per milliliter (CFU/ml), *Legionella* growth appears well controlled.
- If >1 CFU/ml, conditions may allow for *Legionella* growth.
- If 10- to 100-fold increase, *Legionella* growth appears to be poorly controlled.
- If >100-fold increase, *Legionella* growth appears to be uncontrolled.

<sup>&</sup>lt;sup>71</sup> "Legionella—Outbreaks" (web page), CDC, accessed March 10, 2023, https://www.cdc.gov/legionella/outbreaks.html.

<sup>&</sup>lt;sup>72</sup> VHA Supplement 1061-1.1, "Legionella Information Sheet," June 29, 2022.

# **Appendix B: Scope and Methodology**

### Scope

The audit team conducted its work from August 2022 through July 2023. The team selected four facilities for site visits—the VA medical centers in Salem, Virginia; Brooklyn, New York; Pittsburgh, Pennsylvania; and Dublin, Georgia—to determine if medical facilities were meeting VA's water safety and reporting standards for potable water distribution systems during the audit period from April 1, 2021, through March 31, 2022.

## Methodology

To achieve the objective, the audit team reviewed VA directives, policies, procedures, and other applicable guidance related to the prevention and control of *Legionella*.

The audit team interviewed VA facility staff, including the medical facility directors, associate directors, chief engineers, members of the facility water safety committee, facilities maintenance staff, and VA contractors who are involved in water testing and remediation. The team also conducted interviews with the Veterans Integrated Service Network (VISN) director, the VISN capital asset manager, and the VISN water safety committee liaisons. In addition, the team conducted multiple interviews with the director of healthcare engineering and the associate director of the Veterans Health Administration (VHA) National Infectious Diseases Services regarding program oversight.

To determine VHA's compliance with VHA Directive 1061 for addressing the prevention and control of *Legionella* for potable water distribution systems, the team reviewed facility routine water testing results for potable water in all buildings that were tested for *Legionella*, facility-and building-specific healthcare-associated *Legionella* disease prevention plans, laboratory reports from VA or third-party laboratories for all routine water samples and post-remediation water samples, facility mitigation and remediation processes, quarterly and annual reports of water system maintenance and monitoring, and any applicable issue briefs.

#### **Internal Controls**

The audit team assessed the internal controls of VHA Directive 1061 that were significant to the audit objective. This included an assessment of the five internal control components: control environment, risk assessment, control activities, information and communication, and monitoring.<sup>73</sup> In addition, the team reviewed the principles of internal controls as associated with the objective. The team identified all five components and 12 principles as significant to the

<sup>&</sup>lt;sup>73</sup> Government Accountability Office (GAO), *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

objective. The team identified internal control weaknesses during this audit and proposed recommendations to address the following control deficiencies:

- Component 1: Control Environment
  - o Principle 2: Exercise Oversight Responsibility
  - o Principle 3: Establish Structure, Responsibility, and Authority
  - o Principle 5: Enforce Accountability
- Component 2: Risk Assessment
  - o Principle 6: Define Objectives and Risk Tolerances
  - o Principle 7: Identify, Analyze, and Respond to Risks
- Component 3: Control Activities
  - o Principle 10: Design Control Activities
  - o Principle 11: Design Activities for the Information System
  - o Principle 12: Implement Control Activities
- Component 4: Information & Communication
  - o Principle 13: Use Quality Information
  - o Principle 14: Communicate Internally
- Component 5: Monitoring Activities
  - o Principle 16: Perform Monitoring Activities
  - o Principle 17: Evaluate Issues and Remediate Deficiencies

#### Fraud Assessment

The audit team assessed the risk that fraud and noncompliance with provisions of laws, regulations, contracts, and grant agreements, significant within the context of the audit objectives, could occur during this audit. The team discussed the potential fraud indicators and exercised due diligence in staying alert to any fraud indicators throughout the audit. The OIG did not identify any instances of fraud or potential fraud during this audit.

## **Data Reliability**

The audit team obtained routine water testing and post-remediation testing results for potable water from Water Safety Management Tool (WSMT). To test the reliability and completeness of WSMT data, the audit team verified water sample results for the four medical facilities within

the scope of this audit using either third-party laboratory reports or laboratory databases. During this audit, the team identified that all four facilities were reporting incomplete or inaccurate water sample results in WSMT, as discussed in the report finding. For any analysis conducted using WSMT data, the audit team obtained and also used all corresponding source laboratory data to ensure reliability. Therefore, the team concluded the data was sufficiently reliable to meet the audit's objective.

#### **Government Standards**

The OIG conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that the OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions based on audit objectives. The OIG believes the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objectives.

## **Appendix C: VA Management Comments**

#### **Department of Veterans Affairs Memorandum**

Date: September 13, 2023

From: Under Secretary for Health (10)

Subj: OIG Draft Report, VHA Should Continue to Improve Water Safety and Oversight of Prevention Practices to Minimize the Effects of Legionella (Project # 2022-03247-AE-0132) (VIEWS 10684234)

To: Assistant Inspector General for Audits and Evaluations (52)

- Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report, VHA Should Continue to Improve Water Safety and Oversight of Prevention Practices to Minimize the Effects of Legionella. The Veterans Health Administration (VHA) concurs with recommendations 3, 4, 5 and 7 and concurs in principle with recommendations 1, 2, 6 and 8. VHA provides an action plan in the attachment.
- 2. VHA takes our water safety program seriously and the OIG review will assist us with improving program implementation at the four sites reviewed and at our VHA buildings across the country. As noted in the draft report, the occurrence of healthcare-associated Legionella disease in patients or residents with overnight stays at VA medical facilities is very low which support our prioritization of the program. This is an important milestone for VHA's Legionella prevention program, especially for a large healthcare system with hundreds of buildings.
- 3. VHA has long prioritized prevention of healthcare-associated Legionella disease and has had national Legionella prevention policy in place for several decades. VHA Directive 1061(1), Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems, is a leading example in the nation for water management in healthcare and predates similar Legionella prevention documents from regulatory (Centers for Medicare & Medicaid Services), accreditation (The Joint Commission), and standards (American Society of Heating, Refrigerating and Air-Conditioning Engineers) organizations. Currently, the Centers for Disease Control and Prevention includes the Directive on its website and the policy serves as an example to other healthcare systems looking to develop their own Legionella prevention programs.
- 4. It is noted that the audit period of April 1, 2021 through March 31, 2022 occurred during the COVID-19 pandemic, a time when multiple healthcare operations were affected and specific accommodations were allowed by VHA Central Office regarding some of the water testing requirements in VHA Directive 1061. Therefore, although maintaining proper engineering controls to limit Legionella growth in water systems was still required throughout the pandemic, local water testing practices may have changed, affecting evaluations of compliance.

The OIG removed point of contact information prior to publication.

(Original signed by)

Shereef Elnahal. M.D., MBA.

Attachments

Attachment

# VETERANS HEALTH ADMINISTRATION (VHA) Action Plan

OIG Draft Report, VHA Should Continue to Improve Water Safety and Oversight of Prevention Practices to Minimize the Effects of Legionella (2022-03247-AE-0132)

Recommendation 1: The assistant under secretary for health for support should establish review and certification procedures for Veterans Integrated Service Network's to ensure medical facilities' healthcare-associated Legionella disease prevention plans for buildings comply with Veterans Health Administration Directive 1061 requirements.

**VHA Comments:** Concur in principle. VHA Directive 1061(1), *Prevention of Health Care-Associated Legionella Disease and Scale Injury From Water Systems*, published February 16, 2021, already establishes the requirement for the Veterans Integrated Service Networks (VISNs) to review VA Medical Facility health care-associated *Legionella* disease prevention plans (see paragraph 5.f.(3)). Additionally, there are details in the directive defining the requirements of the plans. To ensure that the review is completed, VHA will institute an annual VISN certification process to ensure medical facility compliance with the requirements in the directive.

Status: In progress Target Completion Date: December 2023

<u>Recommendation 2</u>: The assistant under secretary for health for support should develop and ensure Veterans Integrated Service Network's perform and document quality control and quality assurance checks of their requirements for oversight and enforcement of the Veterans Health Administration Directive 1061 quarterly Legionella water testing procedures conducted by the facility.

**VHA Comments:** Concur in principle. VHA Directive 1061(1), *Prevention of Health Care-Associated Legionella Disease and Scale Injury From Water Systems*, published February 16, 2021, already establishes the requirement for the VISNs to ensure that all VA Medical Facilities comply with the requirements of the directive (See paragraph 5.f.(1)). To ensure that the VISNs are completing the required reviews and verifying their review process with quality control/quality assurance checks, VHA will institute an annual VISN certification to confirm oversight of quarterly Legionella water testing at medical facilities.

Status: In progress Target Completion Date: December 2023

Recommendation 3. The assistant under secretary for health for operations should monitor Veterans Integrated Service Network officials fulfillment of their oversight responsibilities found in Veterans Health Administration Directive 1061 regarding Legionella water sampling, testing, remediation efforts, and reporting of Legionella water testing data, including the post-remediation test results.

**VHA Comments:** Concur. VHA will institute an annual VISN certification process to confirm that VISNs are providing oversight of Legionella water sampling, testing, remediation efforts and reporting of Legionella water testing data, including the post-remediation test results at medical facilities.

Status: In progress Target Completion Date: December 2023

Recommendation 4. The director of the Office of Healthcare Engineering should consider alternative measures, such as adding dedicated resources to provide expertise and support for medical facilities experiencing persistent positive Legionella in facility water supply systems after applying the remediation efforts prescribed by Veterans Health Administration Directive 1061.

**VHA Comments:** Concur. VHA will evaluate the ability to add dedicated staff to provide support and oversight of the national water safety program including providing expertise and support for medical facilities experiencing persistent positive *Legionella* in facility water supply systems after applying the remediation efforts prescribed by VHA Directive 1061(1).

Status: In progress Target Completion Date: December 2023

<u>Recommendation 5.</u> The director of Office of Healthcare Engineering should assist the Salem VA medical center with their persistent positive Legionella in the facility water supply system, and, with consideration of the ongoing water supply system renovations, develop an action plan to mitigate remediation challenges.

**VHA Comments:** Concur. VHA will work with VISN 6 to support the Salem VA Medical Center in evaluating their engineering controls and remediation processes for the management of *Legionella* in their system.

Status: In progress Target Completion Date: December 2023

Recommendation 6. The director of the Office of Healthcare Engineering should clarify the responsibility section of Veterans Health Administration Directive 1061 to clearly define oversight responsibilities for ensuring required remediation steps are completed when facilities received positive Legionella water test results.

VHA Comments: Concur in principle. The oversight responsibilities for remediation are currently in VHA Directive 1061(1) in several different sections (see paragraph 5.h.(2), 5.h.(3)(a), 5.h.(4)) and Appendix A, paragraph 4.a. of the directive requires the facility Water Safety Committee to determine the remediation actions to take and to what extent. VHA will update the language in paragraph 5.m., the responsibilities section for the VA Medical Facility Water Safety Committee Chair, to further clarify the oversight responsibilities for ensuring required remediation steps are completed when facilities received positive Legionella water test results.

Status: In progress Target Completion Date: December 2023

<u>Recommendation 7.</u> The director of the Office of Healthcare Engineering should revise the Water Safety Management Tool to alert Veterans Integrated Service Network and medical facility oversight officials when quarterly testing data is not posted.

**VHA Comments:** Concur. VHA will update the Water Safety Management Tool to include an alerting function to notify VISN and medical facility oversight officials when quarterly water testing data are not posted.

Status: In progress Target Completion Date: December 2023

Recommendation 8. The assistant under secretary for health for operations should take actions to confirm that Veterans Integrated Service Network officials are ensuring front-line staff are routinely notified by responsible medical facility officials when elevated Legionella water sample levels require diagnostic awareness and additional clinical surveillance of veterans to detect Legionnaires' disease.

VHA Comments: Concur in principle. VHA Directive 1061(1) paragraph 5.i.(3) requires the facility Chief of Staff (COS) and the Associate Director of Patient Care Services (ADPCS) to notify clinical staff at the facility of environmental testing positive findings. Paragraph 5.m.(8) in the directive requires the Water Safety Committee Chair to notify medical facility leadership (which includes the COS and ADPCS) of environmental testing positive findings. VHA will develop a certification process for medical facilities to confirm that this notification is occurring as required by the directive. Certification of VISN oversight is addressed in the response to Recommendations 1 and 2.

Status: In progress Target Completion Date: December 2023

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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