



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

OCT 07 2014

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-13-4538

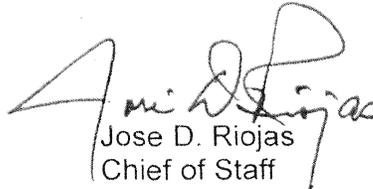
Dear Ms. Lerner:

I am responding to your request for supplemental information on the Department of Veterans Affairs (VA) investigation into allegations by a whistleblower at the VA Medical Center in Grand Junction, Colorado (hereafter, the Medical Center). The whistleblower's primary allegation was that management has engaged in conduct that may constitute a substantial and specific danger to public health and safety by failing to properly address unsafe conditions that pose health and safety hazards to patients and staff. He specifically alleged failures with *Legionella* testing, *Legionella* eradication procedures, and with the maintenance and cleaning procedures required to prevent *Legionella* bacteria growth. Our original report was submitted to your office October 31, 2013, and it contained eight recommendations for the Medical Center, all endorsed by former Secretary Eric Shinseki.

Following the report, the Medical Center submitted an action plan that addressed all eight report recommendations. The Medical Center has successfully completed six actions and is appropriately managing the two remaining ones. In the interim, the Office of Special Counsel raised several additional questions about the investigation at the Medical Center. The enclosed supplemental report responds to these questions, and provides details on the status of the Medical Center's eight action items. In addition, the Veterans Health Administration has recently published a new directive on *Legionella* that will enable this and other VA medical centers to more effectively manage the bacteria.

Thank you for the opportunity to respond.

Sincerely,



Jose D. Riojas
Chief of Staff

Enclosure

**Department of Veterans Affairs Supplemental Report
to the
Office of Special Counsel
Grand Junction Veterans Affairs Medical Center
Grand Junction, Colorado
July 29, 2014**

TRIM 2014-D-1034

Reponses to the Office of Special Counsel (OSC) follow-up questions on Grand Junction VA Medical Center - OSC File No. DI-13-4538.

1. The report substantiated that the Grand Junction VA Medical Center (hereafter, the Medical Center) did not comply with VHA Directive 2008-010, *Prevention of Legionella Disease*, in conducting eradication procedures following the detection of *Legionella* in February 2013. However, the Office of the Medical Inspector (OMI) found that the Medical Center had conducted thermal eradication procedures (superheat and flush) weekly since March 2013.

OSC requests the date on which eradication procedures were first properly conducted in compliance with VHA Directive 2008-010, i.e., with the required temperature, for the proper length of time, and in accordance with all other required procedures.

VA Response: The Medical Center conducted eradication procedures in complete conformance with the Directive beginning October 23, 2013, utilizing copper/silver ionization generators. In addition, the Medical Center continues to maintain temperatures in its hot and cold water systems in compliance with the Directive.

From March through October 2013, the Medical Center utilized thermal eradication as an interim mitigation technique in selected areas of the hospital, while they were working on a more permanent solution. During this time, the Medical Center never conducted thermal eradication in full compliance with the Directive, due to a number of reasons including: rooms being occupied by patients preventing the flushing of fixtures in the room, mixing valves that prevented the water from reaching the prescribed temperatures, and automatic sink and shower valves that prevented the prescribed flushing times for some fixtures. On or around April 5, 2013, the Medical Center planned to procure and install copper/silver ionization generators for each of its three hot water sub-systems (in Building 1 and Building 20) as a long-term, *Legionella* mitigation/control action in compliance with the Directive.

Copper/silver ionization generators are a commodity purchase. The Medical Center sent a solicitation package (575-13-816A) for the equipment purchase to Veterans Integrated Service Network (VISN) 19 contracting on May 7, 2013, which awarded the contract on June 27, 2013. The equipment arrived on station September 6, 2013. The Medical Center required a separate service contract to install the system, and sent the solicitation package to VISN 19 contracting on June 3, 2013. They awarded the contract (project 575-12-816B) on July 20, 2013.

The Medical Center needed the approval of the City of Grand Junction before utilizing the copper/silver ionization generators. On or about September 10, 2013, the Medical Center's Green Environmental Management System Coordinator contacted the City of Grand Junction's Industrial Pretreatment Department Supervisor, Eileen List, for wastewater discharge permit requirements. On September 13, 2013, the Medical Center submitted the formal application package for a wastewater discharge permit to the City of Grand Junction's Industrial Pretreatment Department. On October 14, 2013, the city granted the Medical Center the permit for discharge of copper/silver ionization system effluent into the City of Grand Junction's sanitary sewer system.

Under project 575-12-816B, the Medical Center began active construction on August 26, 2013, and on October 21–25, 2013, commissioned the copper/silver ionization generators. October 23, 2013, is considered the official start-up date for the system. The Medical Center has been monitoring both copper levels and pH, both of which are in compliance with system requirements.

2. OMI substantiated the need for additional mitigation measures beyond thermal eradication, as there are areas within the VAMC's system where thermal eradication is not feasible.

OSC requests information on any additional or alternative mitigation measures that have been implemented to cover those areas.

VA Response: As noted above, the Medical Center installed copper/silver ionization generators for mitigation and prevention to combat areas within the system where thermal eradication was not feasible.

3. **OSC requests information on the most recent results of testing for *Legionella* in the VAMC's water system.**

VA Response: After installation of the copper/silver ionization generators, there has been a decrease in *Legionella* detection in the water systems at the Medical Center. *Legionella* detection in the water systems is reported as numbers of colony-forming units that grow from sampled sites. In the 8 months prior to the installation of the copper/silver ionization generators, the Medical Center's *Legionella* positive detection rates averaged 50 percent, with multiple sites yielding more than 15 colony-forming units. Over the 8 months since the installation of the copper/silver ionization generators, the Medical Center's positive detection rates have averaged 5 percent and all detections have been less than one colony-forming unit per sample. In every case of a positive detection, the Medical Center has responded with a progressive program of increasing the rate of flushing lines and cleaning, rerouting, or replacing plumbing.

4. OMI substantiated that the VAMC did not completely address unsafe conditions that could potentially pose health and safety hazards to Veterans and staff. The report states that the VAMC conducted a review of all pneumonia cases since the report of positive *Legionella* test results and found no cases *Legionella* pneumonia.

OSC requests additional information regarding this review, including who conducted the review, the specific time frame of the cases reviewed, and how it was determined that cases were not associated with *Legionella*.

VA Response: The Centers for Disease Control and Prevention in their National Center for Immunizations and Respiratory Diseases, *Legionellosis Case Report*, question 19, defines the following terms for health care-associated *Legionella* pneumonia.

1. Definitely: Patient was hospitalized or a resident of a long-term care facility for the entire 10 days prior to onset.
2. No: No exposure to a health care facility in the 10 days prior to onset.
3. Possibly: Patient had exposure to a health care facility for a portion of the 10 days prior to onset.

All records of patients hospitalized from 2000 through 2013 were electronically screened to identify diagnoses that were potentially associated with *Legionella*. The Medical Center accomplished this screen utilizing multiple avenues. It queried the local Health Department Report index for *Legionella pneumophila*. They identified all Veteran records with any form of *Legionella* testing. They also created a clinical reminder using a taxonomy that included both the active and inactive code 482.80 Legionnaire's Disease and had their primary care teams review the screen.

The Medical Center identified five cases of possible *Legionella* by these methods. These cases were forwarded to the Chief of Staff, the senior medical physician at the Medical Center, who reviewed the cases with the Chief of Medicine. After a detailed review of each record, only one Veteran was determined to have had *Legionella* pneumonia. This Veteran spent 2 days at a local community hospital prior to being transferred to the Medical Center on October 10, 2008, with a diagnosis of pneumonia. His most recent encounter at the Medical Center had been on July 9, 2008, 91 days prior to admission. This indicates that the Veteran in question had acquired the *Legionella* infection in the community, not at the Medical Center, since it had been more than 10 days since his last Medical Center contact. The Medical Center staff tested the Veteran for *Legionella*. While awaiting the results of the *Legionella* titers test and in response to the Veteran developing a rash to the antibiotics started at the community hospital, the Medical Center staff changed the Veteran's antibiotics to include *Legionella* coverage, and transferred him to the Denver VA Medical Center for a higher level of care. While the Veteran was hospitalized in Denver, the Medical Center received his positive *Legionella* titer test results, and reported them to his caregivers in Denver. His treatment was appropriate for *Legionella*, and the Veteran recovered.

Additionally, the Infection Preventionist reviewed a total of 202 patient charts as part of the ongoing auditing for infections at the Medical Center. From October 1, 2013, to June 30, 2014, 137 patients met the criteria for *Legionella* urine antigen testing (anyone admitted with a suspected pneumonia). The laboratory reports these results to the Infection Preventionist on a daily basis. One Veteran, of the 137 tested, had a positive *Legionella* urine antigen; he had reported to the emergency department on December 1, 2013, with a 1-day history of shortness of breath and a

shallow nonproductive cough. The Infection Preventionist reviewed the Veteran's prior encounters at the Medical Center and found that he had received an influenza vaccination on October 28, 2013 (33 days prior to his admission), but had not otherwise been in the facility since August 2013. Medical staff diagnosed the infection as community-acquired, based on the CDC guidelines. The Infection Preventionist reported his case to the local health department.

5. The agency report includes eight recommendations made by OMI for corrective actions to be taken by the VAMC.

OSC requests information regarding the status of each of these recommended actions, as well as any other actions taken or planned by the VAMC.

Recommendation 1: Ensure that the Medical Center's *Legionella* policy is updated with specific and feasible mitigation plans.

Resolution: Prior to June 17, 2013, the Medical Center's Nursing Service managed the Legionnaire's Disease Prevention Program using the Medical Center Memorandum (MCM) #003-39 as guidance. Secondary to the detection of the *Legionella* in the water system, the Medical Center formed a Water Safety Committee, which became responsible for the *Legionella* detection and eradication efforts. The Chief of Engineering and the Safety Department, with the Medical Center leadership's concurrence, updated Medical Center Memorandum 007-26, *Legionnaire's Disease Prevention Program*, including their specific mitigation plan on October 24, 2013.

Action Completed

Recommendation 2: Update Medical Center Engineering Service Policy Memorandum 5.42, *Domestic Hot Water System Superheat and Flush Procedures*, to accurately identify components of the hot water distribution system and temperature set points in accordance with VHA Memorandums.

Resolution: The Chief of Engineering originally put Engineering Service Policy 5.43 in place on July 15, 2013. The Medical Center received OMI's initial recommendations on or around November 22, 2013. In addition, on February 19, 2014, an outside consultant hired by VISN 19 conducted a Hazard Analysis Critical Control Point Survey, a comprehensive review of the facility's potable water system, and a program "based on the Hazard Analysis and Critical Control Point approach, which is a process for identifying risk and implementing control measures to reduce risk associated with *Legionella* in water systems." They based their review on the anticipated new standards more stringent than the current directive. The Medical Center is actively responding to both the OMI's and the Hazard Analysis Survey's recommendations and has implemented many of the actions, some more frequently than recommended in the reports. The Medical Center revised its policy to include OMI's recommendations regarding components of the hot water system and the temperature set points on March 12, 2014.

Action Ongoing

Recommendation 3: Update the Medical Center Engineering Service Policy Memorandum 5.43, *Domestic Hot Water System Superheat and Flushing*, to include thermal eradication parameters established in the VHA Directives.

Resolution: The Chief of Engineering updated the *Engineering Service Policy 5.43, Domestic Hot Water System Superheat and Flushing*, to include temperature and duration parameters on March 12, 2014.

Action Completed

Recommendation 4: Ensure that the selected *Legionella* mitigation procedure conducted to eradicate the *Legionella* growth is done in accordance with the above VHA Directive, i.e., if thermal eradication is used, ensure that all valves are flushed for 30 minutes with superheated (160–170°F) water.

Resolution: As stated above in Recommendation 3, the Chief, Engineering updated the Engineering Service Policy 5.43 to include preventive maintenance temperature and duration parameters in accordance with the VHA Directive on prevention of *Legionella* disease on March 12, 2014. In addition, he also installed the copper/silver ionization generators, which cover areas where thermal eradication is not possible.

Action Completed

Recommendation 5: Prior to implementing mitigations, ensure that all involved staff understand mitigation procedures, safety precautions, and document training.

Resolution: The Chief, Engineering, also updated Engineering Service Policy 5.43 to include a requirement to conduct a safety briefing prior to superheating and flushing procedures. In addition, Medical Center leadership changed the facility's primary mitigation measure from thermal eradication to the copper/silver ionization generators. Engineering leadership provided training to the plumbers and other engineering staff prior to initiating these systems on October 23, 2013. The Medical Center notified all facility staff of the changed mitigation plan utilizing multiple venues: the Employee Forum on November 14, 2013, a "Prevention Focus" electronic newsletter on December 20, 2013, and various committee and staff meetings.

Action Completed

Recommendation 6: Consider expanding the building automation system to include temperature monitoring throughout the Medical Center.

Resolution: Currently, the Medical Center manually monitors the temperatures throughout the system on a daily basis. In addition, the Medical Center's Green Environmental Management System Coordinator checks temperatures during the monthly sample collections for *Legionella* testing. The building automation system is a way to automate this ongoing work. The Engineering staff submitted a contract, "Project #575-13-105 (Correct Retro-CX deficiencies and upgrade

HVAC controls),” which includes the installation of thermal sensors within the hot water system, to the VISN 19 contracting office. The project title was awarded (PO#: 575C44097/Contract #: VA259-14-C-0395) on September 25, 2014, for the amount of \$151,514.11. The project title was changed to Water Temperature Monitoring for Legionella Mitigation (project #: 575-14-109).

Action Ongoing

Recommendation 7: Develop preventive maintenance procedures for semi-instantaneous water heaters, using the manufacturer's requirements, as the basis for establishing time intervals and work to be performed.

Resolution: The Chief, Engineering, developed Engineering Service policy 5.45, *Domestic Hot Water Treatment Operation and Maintenance of Semiline Stream Boilers*, that outlines procedures for the preventive maintenance of semi-instantaneous water heaters, using the manufacturer's requirements as the basis for establishing time intervals and work on March 11, 2014.

Action Completed

Recommendation 8: Ensure redundancy in the water heating system supplying the Community Living Center (CLC).

Resolution: To ensure redundancy in the CLC water heating system, the Engineering staff completed an interconnection between Building 1 and the CLC systems on June 26, 2014.

Action Completed

6. OSC deems an agency-wide directive to be a law, rule, or regulation. The agency report confirms that the Grand Junction VAMC did not comply with VHA Directive 2008-010 when conducting eradication procedures. Nevertheless, the report concludes that the investigation did not reveal violations or apparent violations of statutory laws, mandatory rules, or regulations.

OSC requests clarification of the agency's basis for this conclusion.

VA Response: VA does not consider agency policies such as handbooks and directives to rise to the level of “law, rule, or regulation” and we have been unable to find OSC's definition of this phrase. Instead, we have interpreted law, rule, or regulation to mean statutory laws, as codified in the United States Code, agency regulations, as found in the *Code of Federal Regulations*, or rules, such as Executive Orders. Therefore, we have consistently stated in reports to OSC that when an agency policy is not followed there is no violation of law, rule, or regulation, but that there is noncompliance with VA policies. We are open to having a discussion with OSC regarding the way in which your office defines the phrase “law, rule, or regulation” so that we could use that definition when writing reports responding to future whistleblower disclosures.