



DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

November 6, 2013

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-13-3728

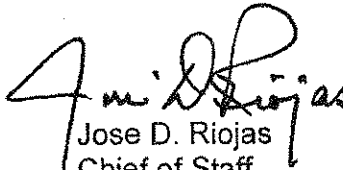
Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Phoenix Department of Veterans Affairs Health Care System (hereafter, the Medical Center) in Phoenix, Arizona. The whistleblower alleged that an employee of the Sterile Processing Service (SPS) failed to regularly and properly clean equipment and to regularly wear protective gear and that management failed to remediate these lapses, possibly constituting a violation of law, rule, or regulation, and gross mismanagement, which could lead to a substantial or specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary under 5 United States Code § 1213(d)(5).

The Secretary asked the Under Secretary for Health to review this matter and to take any actions deemed necessary under the above code. He, in turn, directed the Office of the Medical Inspector (OMI) to conduct an investigation. In its investigation, OMI did not substantiate the allegation that the employee failed to regularly and properly clean equipment or that the Medical Center failed to take corrective action. Regarding the allegation that the employee did not wear protective gear, OMI could not find sufficient evidence to substantiate this claim. Therefore, we found neither violations of laws, rules, or regulations, nor a substantial or specific danger to public health. OMI did find, however, that the use of personal electronic devices in SPS was a violation of Medical Center policy. OMI made two recommendations regarding general compliance with procedures and one recommendation to continue monitoring the ongoing quality program. Findings from the investigation are contained in this report, which I am submitting for your review.

Thank you for the opportunity to respond.

Sincerely,

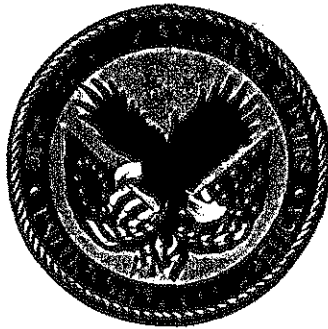

Jose D. Riojas
Chief of Staff

Enclosure

OFFICE OF THE MEDICAL INSPECTOR

**Report to the
Office of Special Counsel
File Number DI-13-3728**

**Phoenix Veterans Affairs
Health Care System
Phoenix, Arizona**



**Veterans Health Administration
Washington, DC**

**Report Date: September 20, 2013
TRIM 2013-D-997**

Any information in this report that is the subject of the Privacy Act of 1974 and/or the Health Insurance Portability and Accountability Act of 1996 may only be disclosed as authorized by those statutes. Any unauthorized disclosure of confidential information is subject to the criminal penalty provisions of those statutes.

Executive Summary

Summary of Allegations

The Under Secretary for Health requested that the Office of the Medical Inspector (OMI) investigate allegations lodged with the Office of Special Counsel concerning the Phoenix Veterans Affairs (VA) Health Care System (hereafter, the Medical Center) by an anonymous whistleblower. The whistleblower alleged that employees are engaging in conduct that may constitute violations of laws, rules, or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. OMI conducted a site visit to the Medical Center on August 26-28, 2013.

The whistleblower alleged that Medical Center employees have regularly failed to properly clean and sterilize reusable medical equipment (RME). In brief, the whistleblower alleged that:

1. A particular Sterile Processing Service (SPS) employee regularly fails to properly clean RME, resulting in the delivery of RME with "bio-burden" to an operating room (OR) and possible damage to delicate equipment;
2. The SPS employee also regularly fails to wear personal protective equipment (PPE) while working within SPS; and
3. Medical Center management has not taken sufficient action to correct or curtail such behaviors.

OMI **substantiated** allegations when the facts and findings support that the alleged events or actions took place. OMI **did not substantiate** allegations when the facts showed the allegations were unfounded. OMI **could not substantiate** the allegations when there was no conclusive evidence to either sustain or refute the allegation.

Conclusions

- OMI did not substantiate the allegation that the SPS employee regularly fails to properly clean RME, resulting in the delivery of RME containing bio-burden to the OR and possible damage to delicate equipment.
- The Medical Center's policy prohibiting the use of personal electronic devices in the decontamination area is clear, and the whistleblower's use of such a device to capture images had the potential of spreading contamination outside of the area.
- The use of an imaging device within the facility is a violation of Medical Center policy.

- While OMI confirmed one occurrence of non-compliance by the SPS employee for not wearing PPE while working in the decontamination area, OMI could not substantiate that the SPS employee regularly fails to wear PPE while working within SPS.
- PPE is for personal protection; thus, the risk would be to the SPS employee for not wearing protective equipment.
- OMI did not substantiate the allegation that Medical Center management failed to take sufficient action to correct or curtail such behaviors. Instead, OMI found evidence of a responsive, effective, and approachable leadership team with excellent documentation.

Recommendations

The Medical Center should:

1. Ensure that SPS personnel are aware of the policies regarding the use of electronic devices (both cameras and telephones) within the decontamination area.
2. Monitor compliance related to the required PPE in the decontamination area and address non-compliance as indicated.
3. Continue its monitoring of end-product delivery of sterilized equipment as part of its ongoing quality assurance program.

Summary Statement

Based on OMI's investigation and VA's Office of General Counsel's review of its findings, there was no determination of violations of statutory laws, mandatory rules, or regulations.

I. Introduction

The Under Secretary for Health requested that the Office of the Medical Inspector (OMI) investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Phoenix Veterans Affairs (VA) Health Care System (hereafter, the Medical Center) by an anonymous whistleblower. The whistleblower alleged that employees are engaging in conduct that may constitute violations of laws, rules, or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. OMI conducted a site visit to the Medical Center on August 26-28, 2013.

II. Facility Profile

The Phoenix VA Health Care System includes a complexity level 1c tertiary care facility and 6 community-based outpatient clinics located in Mesa, Central Phoenix, Payson (Contract), Show Low, Globe, and Surprise, Arizona. The Medical Center is a teaching hospital, providing a full range of patient care services, with state-of-the-art technology and research. Comprehensive health care is provided through primary care, long-term care, and tertiary care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, nutrition, geriatrics, and extended care. Comprised of 177 inpatient beds and 104 community living center beds, the Medical Center maintained an average daily census of 163 and a 59-percent occupancy rate; had 779,197 outpatient visits; and performed 3,827 surgical procedures during fiscal year (FY) 2012.

The Medical Center has over 464 affiliation agreements with over 145 institutions and supports and funds over 80 resident positions at the facility each year. The Medical Center has fully integrated training programs with Banner Good Samaritan in family medicine, general surgery, oral maxillofacial surgery, internal medicine, obstetrics and gynecology, orthopedics, psychiatry, cardiology, endocrinology, gastroenterology, geriatrics, and pulmonary/critical care medicine; with Maricopa Integrated Health System in psychiatry and radiology; and with Mayo School of Graduate Medical Education in dermatology, otolaryngology, and gastroenterology. The Medical Center has an active affiliation with the University of Arizona College of Medicine-Phoenix and is also involved in the educational programs of Midwestern College of Osteopathic Medicine and A.T. Still University. There are nursing affiliations with Arizona State University, University of Phoenix, Grand Canyon University Chamberlain College, Northland Pioneer College, and the Maricopa Community Colleges.

III. Conduct of Investigation

An OMI team consisting of (b) (6) M.D., Deputy Medical Inspector for Professional Services (a surgeon); (b) (6) M.D., Medical Investigator (an internist); (b) (6) Registered Nurse (RN), Clinical Program Manager; (b) (6) Nurse Practitioner, Clinical Program Manager; and (b) (6) RN, Health Systems Specialist, Veterans Health Administration (VHA) National Program Office for Sterile Processing (subject matter expert), conducted the investigation. OMI

located in the wall that separates the decontamination area from the preparation and assembly area and are loaded from the decontamination side. When the cleaning cycle finishes, the contents of the washers are automatically ejected onto a conveyor belt to dry then unloaded from the conveyor belt by technicians in the preparation and assembly area. After arrival in the preparation and assembly area, all instruments are inspected, and any instruments noted to still have debris present after cleaning are returned to the decontamination area via a pass-through window located in the wall separating the two areas. After passing inspection, the technician packages them for sterilization. Items are placed in trays, wrapped, and secured with both internal and external sterilization indicator labels and placed into the sterilization machine. The labels change in appearance during the sterilization process. Upon completion of sterilization, the equipment is placed into the distribution system for delivery. At the end user site, the instrument sets are opened by technicians wearing sterile personal protective equipment (PPE) and inspected again prior to use. If any contamination is found, the instrument set is returned to the decontamination area for reprocessing. The OR tracks any issues related to equipment provided by SPS with incident reports.

V. Allegation 1

The whistleblower alleged that a particular SPS employee regularly fails to properly clean RME, resulting in the delivery of RME with bio-burden to an OR and possible damage to delicate equipment.¹ In the OSC letter, the whistleblower identified the particular SPS employee as (b) (6) SPS technician during the day shift (hereafter, the SPS employee).

Findings

The SPS employee is responsible for ensuring instruments are reprocessed correctly and efficiently by all technicians and for addressing any instrument-related issues. He is expected to provide hands-on support as needed in the decontamination and preparation areas. All SPS technicians are trained and certified at either Level I or Level II by VA Central Office (VACO). To obtain this certification, technicians must successfully complete comprehensive training courses covering standards and criteria for SPS, including the principles of decontamination, packaging, sterilization, storage, and distribution of medical/surgical devices, infection control/prevention, disease transmission, microbiology, and terminology. Successful completion of Level I is required before the technician can begin Level II training. At the completion of Level II training, participants may take the VACO Level II SPS certification examination.

According to information provided by the whistleblower, the SPS employee frequently states the SPS decontamination processes are too slow and that the technicians should work faster. During the OMI visit, two of the five non-supervisory SPS technicians interviewed stated they heard the SPS employee instruct staff members to work faster,

¹ Bio-burden is the population of viable microorganisms on surgical instruments or medical devices (www.infectioncontroltoday.com). It is also used to describe debris that may or may not have viable microorganisms.

but no one confirmed that he had said the processes were too slow. SPS leadership confirmed that at times some technicians' personal conversations, either on the telephone or face-to-face, interfere with working efficiently. It is the team leaders' responsibility to ensure that employees work efficiently. OMI found no evidence that the SPS employee's instructions to "work faster" have negatively impacted SPS' ability to consistently provide sterile instruments for use in the OR.

The whistleblower alleged that on (b) (6) 2012, the SPS employee instructed another employee to place a drill bit in the ultrasonic cleaner without scrubbing it to remove bio-burden. Because the item was not adequately scrubbed, it emerged from the cleaner still containing bone and tissue fragments. According to the whistleblower, the drill bit was included in a surgical instrument tray, which upon opening, "contaminated the sterility of the OR, resulting in cancellation of the procedure, the patient being sent home, and the resterilization of the OR." Allegedly, the SPS employee also failed to identify bio-burden on associated instruments.

There is no evidence that the SPS employee instructed another employee to place a drill bit in the ultrasonic cleaner before scrubbing it to remove bio-burden. No technicians interviewed had any recollection of this event, and there is no documentation regarding it in an incident report.

There is no evidence that the SPS employee failed to identify bio-burden on other associated instruments. A review of OR incident reports from October 2012 through August 2013 indicates there were three occurrences when bio-burden was found on sterilized instruments received in the OR from SPS; however, OMI could not find documentation that any of these instruments were reprocessed or packaged by the SPS employee. In addition, none of these incidents occurred on (b) (6) 2012.

OMI reviewed the three occurrences where bio-burden was found on sterilized instruments received in the OR from SPS. In one occurrence, the identification of bio-burden was made after the instrument had been used on a patient; however, a review of the Veteran's medical record shows no evidence of postoperative complications. The second occurrence involved the discovery of bio-burden on an instrument that had not been used on a patient; the instrument was removed from the sterile field, gloves were changed, and the operation was completed. The third occurrence involved the discovery of bio-burden on a loaner instrument after the patient was anesthetized but prior to the start of the case. The Medical Center did not have a second loaner set; therefore, the procedure was aborted, and the patient discharged and rescheduled for a later date. In this instance, the room was cleaned in preparation for the next case in accordance with the usual procedures after a room turnover. The discovery of an instrument with bio-burden in the OR does not contaminate the OR. ORs are cleaned, not sterilized.

The SPS area reprocesses, on average, 1,698 instruments per week. During the 11-month period between October 2012 and August 2013, SPS would have been expected to process at least 74,712 instruments. The three incidents of instruments

with bio-burden discovered in the OR represents about 0.004 percent of instruments processed.

OMI received copies of 11 photographic images. The pictures were reviewed with multiple SPS technicians who described them as images of instruments soiled with blood, tissue, and bone fragments. They reported that the images appeared to be taken in the decontamination area based on the baskets and trays in which the instruments were placed. OMI was unable to verify whether the pictures were taken before or after the instruments had been cleaned. No one reported witnessing the pictures being taken and could not verify whether these images were of instruments that had just been received from the OR after use or if they were instruments that had been sent back to decontamination because of inadequate cleaning. None of the technicians were able to verify that the images were of instruments that the SPS employee had cleaned. When questioned, leadership was not aware of the existence of these photographs; however, two SPS technicians reported seeing them but could not confirm where in the reprocessing sequence these photographs were taken. The technicians interviewed were able to articulate the names and types of instruments captured in the photographs, along with the cleaning process for each.

According to Medical Center Policy Memorandum No. 132-03, *Veterans Affairs Medical Center Security and Law Enforcement*, patients, visitors, and employees are not permitted to take photographs without prior authorization of the Public Affairs Officer. While most employees interviewed were aware of the Medical Center's policy that prohibits taking pictures in the facility, a few indicated that they were unaware of it.

The whistleblower also alleged that on (b) (6) 2013, the SPS employee placed a rigid fiberoptic scope and attachments for a Stryker System 6 handheld cordless power tool into an ultrasonic cleaner "in order to save time." Technicians interviewed did not witness the SPS employee placing any of these scopes in the ultrasonic washer, and there is no documentation relating this incident to the SPS employee. In addition, several of the employees, including the SPS employee, informed OMI that the image depicting these items in the ultrasonic basket was strange as those instruments would never be grouped together. OMI was unable to confirm that the SPS employee placed a rigid fiberoptic scope in the washer; however, a somewhat similar event was reported to leadership involving the other lead SPS technician instructing an employee to place a scope in a washer. This incident was brought to leadership's attention, and leadership counseled the employee and readdressed the proper processing with the entire staff at the very next weekly in-service training.

The whistleblower alleged that on (b) (6) 2013, the SPS employee also failed to properly clean several suction tips. These tips should be soaked, scrubbed, and flushed with water prior to placement in the ultrasonic cleaner. The whistleblower alleged that, if not cleaned properly, the suction tips can drip blood and tissue onto the clean instrument trays, causing recontamination of the contents of the tray and potential hazard to employees. There is no evidence that the SPS employee failed to properly clean several suction tips on (b) (6) 2013, leading to contamination of clean

instrument trays and a potential hazard to employees. Staff members interviewed did not recall this instance, and there is no documentation of the alleged event.

Multiple staff members are responsible for checks on the adequacy of reprocessing instruments, and all technicians interviewed stated, as part of their quality program, they readily return instruments to the decontamination area if the instruments still contain bio-burden and appear in need of additional cleaning.

There was no documentation that the SPS employee's cleaning procedures resulted in damage to delicate equipment. Leadership was not aware of any instrument damage resulting from the SPS employee's cleaning procedures.

Conclusions

- OMI did not substantiate the allegation that the SPS employee regularly fails to properly clean RME, resulting in the delivery of RME containing bio-burden to the OR and possible damage to delicate equipment.
- The Medical Center's policy prohibiting the use of personal electronic devices in the decontamination area is clear, and the whistleblower's use of such a device to capture images had the potential of spreading contamination outside of this area.

Recommendation

The Medical Center should:

1. Ensure that SPS personnel are aware of the policies regarding the use of electronic devices (both cameras and telephones) within the decontamination area.

VI. Allegation 2

The SPS employee also regularly fails to wear PPE while working in SPS.

Findings

The Medical Center must provide PPE to employees to prevent personal injuries from handling contaminated sharp instruments, blood, body fluids, or any other hazardous material during the performance of their instrument decontamination duties. Per *Medical Center Standard Operating Procedures, SPS/90E, Biological Hazards 6004*, and *Safety Awareness in SPS 6007*, PPE required in the decontamination area is long-cuffed rubber or vinyl decontamination specific gloves, head and hair cover, face or eye shield, long-sleeved impervious gown or jumpsuit, and impervious shoe covers or knee high boots. PPE must be donned before entering the decontamination area and must be removed prior to leaving the area. On both the announced and unannounced tours of SPS, OMI observed adequate PPE available for employee use.

The whistleblower alleged that the SPS employee regularly failed to wear PPE while working in SPS, despite being told repeatedly to do so, and does not cover his beard but instead wears a mask around his neck. The whistleblower also alleged that the SPS employee regularly applies lip balm while in SPS.

One technician confirmed an incident during which the SPS employee assisted with the reprocessing of a backlog of instruments and did not wear the proper PPE to protect himself. The SPS employee recounted the same incident, noting he was in a hurry to help, but he was aware of the appropriate protection attire required. Another technician stated that, on a different occasion, she witnessed the SPS employee in the decontamination area without the proper PPE; however, when describing the SPS employee's attire, she described him as wearing items that are acceptable PPE for the decontamination area. No staff members interviewed reported witnessing the SPS employee regularly working in the decontamination area without the proper PPE. The SPS leadership team was not aware of any reports of the SPS employee regularly working in any area of SPS without the appropriate PPE. There were no documented incidents or counseling for the SPS employee related to failure to wear the proper PPE. No staff members interviewed recalled any incidents when the SPS employee did not cover his beard and head as required in SPS. Leadership stated there were no reported incidents that involved the SPS employee failing to wear the appropriate beard, head, or face coverings. A couple of interviewees and the SPS employee reported that he had applied lip balm in the assembly and preparation area but never in decontamination. The application of a lip balm in decontamination would be a risk to the user, not to others. During OMI's scheduled and unscheduled tours, all staff members were observed wearing the proper PPE and could articulate the proper PPE for each area in SPS. Staff education about the required use of PPE is included in annual training.

All staff members are required to change scrubs when leaving the decontamination area. The scrubs worn in the decontamination and preparation areas are uniform in style and similar in color; therefore, unless the scrubs worn in the decontamination area are visibly stained, it would be difficult to determine whether the SPS employee, or any employee, changed scrubs without watching the change in clothes. When leaving the general SPS area, staff members are not required to change scrubs but must wear a long, hospital-issued, buttoned, white jacket to protect the scrubs. During interviews with the SPS technicians, all staff members wore the appropriate covering over their scrubs and could articulate what covering was required when leaving the SPS area. All staff members interviewed stated they are comfortable reminding colleagues to wear the white jacket when leaving SPS.

Conclusion

- While OMI confirmed one occurrence of non-compliance by the SPS employee not wearing PPE while working in the decontamination area, OMI could not substantiate that the SPS employee regularly fails to wear PPE while working within SPS.

- PPE is for personal protection; thus, the risk would be to the SPS employee for not wearing protective equipment.

Recommendation

2. Monitor compliance related to the required PPE in the decontamination area and address non-compliance as indicated.

VII. Allegation 3

Phoenix VA Medical Center management has not taken sufficient action to correct or curtail such behaviors.

Findings

The leadership group in SPS consists of one Chief, SPS; one Assistant Chief, SPS; and two lead SPS technicians assigned to supervise technicians on the day or evening shift. The non-supervisory technicians in SPS report directly to the lead SPS technicians, who report to the Assistant Chief, SPS, who reports to the Chief, SPS. If staff members believe an issue warrants leadership intervention, they are expected to notify their immediate supervisor; if they do not believe the issues have been addressed adequately, they can then notify the Assistant Chief, SPS, followed by the Chief, SPS.

The whistleblower alleged that the Assistant Chief, SPS, was notified that the SPS employee instructed another employee to omit scrubbing the drill bit prior to placing it in the ultrasonic washer, failed to identify remaining bio-burden, and failed to properly clean suction tips. As OMI found for Allegation 1, there is no evidence the SPS employee instructed another employee to omit scrubbing the drill bit prior to placing in the ultrasonic washer, nor did any technicians corroborate the incident occurred. There is no evidence that the SPS employee failed to identify remaining bio-burden or that he failed to properly clean several suction tips. When questioned, the Chief, SPS, and Assistant Chief, SPS, stated they had not been notified of any such occurrence, and there is no documentation that these alleged incidents occurred or were reported to them.

The whistleblower alleged that the Chief, SPS, was shown the photographic images of the suction tips containing bio-burden. OMI showed the photographic images provided by the whistleblower to the Chief, SPS, and Assistant Chief, SPS; both denied ever having seen or being aware of the photographs. There was no documentation indicating that they knew the images existed or had ever been shown the images by the whistleblower.

The whistleblower alleged that the Chief, SPS, was made aware that the SPS employee improperly placed a rigid fiberoptic scope in the ultrasonic washer. No technicians interviewed witnessed the SPS employee placing any of these scopes in the ultrasonic

washer, and no documentation related to this allegation about the SPS employee exists. However, when a similar event occurred with another employee, it was reported to SPS leadership who addressed the issues with the staff member involved and provided additional training to all technicians.

All SPS technicians interviewed individually and during OMI's tours stated leadership consistently follows up on all issues brought to its attention in an effective and timely manner. SPS leaders stated that they have an open-door policy, encouraging any SPS staff member to speak directly with them. The technicians stated they feel comfortable speaking with leadership and are confident any issues raised will be addressed.

The Medical Center has multiple levels of monitoring to ensure delivery of sterile equipment to the end user. It tracks issues identified relating to sterile processing and investigates each event as part of its quality program. The OR staff and the SPS staff meet regularly to review and address an integrated delivery of sterile equipment.

Conclusion

- OMI did not substantiate the allegation that Medical Center management failed to take sufficient action to correct or curtail such behaviors.

Recommendation

3. The Medical Center should continue its monitoring of end-product delivery of sterilized equipment as part of its ongoing quality assurance program.

Attachment A

1. OR Case Cancellation Report for October 2012 through August 2013.
2. Incident Reports related to OR case cancellations from October 2012 through August 2013.
3. In-Service Documentation for the Ultrasonic Washer.
4. Manufacturer's Instructions for Use for Rigid Fiberoptic Scopes.
5. Manufacturer's Instructions for Use for the Stryker System 6.
6. National Program Office for Sterile Processing Information Brochures related to SPS Level I & II Training.
7. Organizational Chart for the Medical Center's SPS.
8. SPS Area Inspection Worksheet Quarter 1, FY 2013.
9. Phoenix VA Health Care System, Policy Memorandum No. 132-03, *Veterans Affairs Medical Center Security and Law Enforcement*.
10. Phoenix VA Health Care System, Policy Memorandum No. SPD/90E-07, *Management of Loaner Instrumentation*.
11. Phoenix VA Health Care System, Standard Operating Procedure, SPS/90E, *Safety Awareness in SPS 6007*.
12. Phoenix VA Health Care System, Standard Operating Procedure, SPS/90E, *Biological Hazards 6004*.
13. Phoenix VA Health Care System, Standard Operating Procedure for *Reprocessing Rigid Fiberoptic Scopes, October 1, 2011*.
14. Phoenix VA Health Care System, Standard Operating Procedure, SPS/90E, *Cleaning, Disinfecting/Sterilization of the Stryker Small Bone System*.
15. Phoenix VA Health Care System, Standard Operating Procedure, SPS/90E, *Instrument Care and Handling 3003*.
16. VHA Electronic Medical Records.