VA | U.S. Department of Veterans Affairs

Office of the General Counsel
Washington DC 20420

JUN 1 1 2014

In Reply Refer To:

The Honorable Carolyn Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M. Street, NW, Suite 300
Washington, DC 20036-4505

RE: OSC File No. DI-13-3174

Dear Ms. Lerner:

Enclosed are the redacted and unredacted supplemental reports for OSC File No. DI-13-3174. We hereby request that your office publish the redacted version.

If you have any questions about this request, please contact Jennifer Gray in the Office of General Counsel at 202-461-7634.

Sincerely,

Renée L. Szybala
Acting Assistant General Counsel

Enclosure

Office of the Medical Inspector
Supplemental Report
to the
Office of Special Counsel
Western New York Healthcare System, Buffalo, New York
OSC File No. DI-13-3174
June 2, 2014
TRIM 2014-D-685

Background

The Department of Veterans Affairs (VA) Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) investigate complaints lodged with the Office of Special Counsel (OSC) by (b)(6) (hereafter, the whistleblower), at the Department of Veterans Affairs (VA), Western New York Healthcare System (VAWNYHS), Sterile Processing Service (SPS) in Buffalo, New York (hereafter, the Medical Center). The whistleblower, a Medical Supply Technician (MST) at the Medical Center from March 2010 to March 2013, consented to the release of her name, and alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule or regulation, gross mismanagement, and a substantial and specific danger to public health and safety. As part of its investigation, OMI conducted a site visit to the Medical Center on December 9–11, 2013.

Based on its investigation, OMI made five recommendations for the Medical Center. These recommendations were endorsed by the Secretary of Veterans Affairs and the USH. OMI and the Veterans Health Administration's (VHA) Office of the Deputy Under Secretary for Operations and Management reviewed the Medical Center's action plan in response to report recommendations; these actions are currently being followed.

OMI's investigative report was submitted to OSC on January 21, 2014. The whistleblower raised five additional issues and requested that an additional employee be interviewed after the original investigation was completed and report submitted to OSC. The contents of this supplemental investigation are included here.

Recommendation 1: The Medical Center should support the ongoing relationship between Dental Office staff and SPS employees to continue their effective communications, with opportunities for information exchange on instrument processing.

Resolution: SPS staff will meet at least monthly with dental staff to ensure open communications, beginning in April 2014, for an informal meeting. Formal meetings will begin in May 2014, to encourage continuing communication.
Action Ongoing

Recommendation 2: The Medical Center should continue their program of providing SPS employees training on the importance of using PPE.

Resolution: Each employee will complete an annual competency on PPE. This year's annual competency assessment occurred between April 2 and April 30, 2014. Supervisors continue to educate, monitor, and address staff on the importance of appropriate PPE. Signs with photos of appropriate PPE are posted within each SPS section.
Action Ongoing

Recommendation 3: In conjunction with Human Resources leadership, the Medical Center should develop an appropriate approach to deal with SPS employees who continue to be noncompliant with PPE use.

Resolution: In consultation with Human Resources, progressive discipline will be taken with employees who are noncompliant with PPE requirements.
Action Ongoing

Recommendation 4: The Medical Center should continue SPS' practice of two-person sterile tray inspections and two-person signature sign-offs on sterile processing product inspections.

Resolution: All assignments that involve an item leaving the department (e.g., case carts, instrument trays, and loaner sets) require a verifier (i.e., second person) signature. This process began in August 2013. Re-education of staff on this practice and policy began on April 1, 2014, and was completed on April 30, 2014.
Action Ongoing

Recommendation 5: The Medical Center should develop a systematic approach to analyzing SPS Close Call quality improvement data. Trending and tracking this information can be used to develop action items and to monitor changes.

Resolution: Close calls are tracked and reported to the SPS staff, as well as to the Reusable Medical Equipment and Infection Prevention Committees. To improve the systematic approach to analyzing close calls, the Medical Center will use a tool designed to address noncompliance and track corrective actions. Development and implementation of the tool will be completed by September 2014. Close calls are reported monthly to the committees. SPS supervisors provide training, as needed.
Action Ongoing

Additional Issues Raised after the investigation was completed and report submitted to OSC

The whistleblower provided additional documentation and requested that OMI interview (b)(6), a certified registered medical supply technician at the Medical Center pertaining to the concerns detailed below. Following (b)(6) interview, OMI re-interviewed (b)(6)., Assistant Chief, SPS.
1. Time and attendance records of several SPS staff

Resolution Issue 1: (b)(6) provided her concerns about the time and attendance records of several SPS staff. OMI does not investigate concerns pertaining to human resources; however, the Medical Center has been made aware of the concerns and is addressing them.
Action Completed

2. The number of SPS competencies required

Resolution Issue 2: (b)(6) said that she was hired as an SPS supervisor in March 2013. She reported that she was tasked with managing the competencies; however, initially, she was personally not signed off on all of them prior to taking on this role. At the time of our interview, (b)(6) reported that all of her competencies had been signed off.
Action Completed

3. Inadequate cleaning of dental cassettes

Resolution Issue 3: (b)(6) reported that some staff members fail to remove and clean underneath the rubber mats that lie within the dental cassettes under the dental instruments. The Assistant Chief, SPS, has reviewed the standard operating procedure with SPS staff and has completed retraining where necessary. OMI is clarifying this issue.
Action Ongoing

4. Inadequate cleaning of the autoclave machine

Resolution Issue 4: The autoclave machine is cleaned on weekends. On a recent Monday, (b)(6) stated that when she reported to work at 3:00 p.m., the inside of the autoclave machine was wet and showed evidence of enzymatic cleaner. (b)(6) reported her concerns to the Assistant Chief, SPS, who in turn removed the machine from use and repeated the cleaning process, reported the autoclave will continue to be cleaned on weekends, and, in addition, that the manufacturer will perform cleaning on a quarterly basis.
Action Completed

5. Concerns regarding infection control related to the location of the SPS housekeeping closet and the condition of the flooring

Resolution Issue 5: The SPS housekeeping closet is currently located within the clean preparation area, which (b)(6) reported as a concern to SPS leadership. SPS leadership has submitted a proposal to Medical Center leadership to relocate the housekeeping closet to a location outside of the clean preparation area.
Action Ongoing

Additional items to be addressed in the supplemental report:

Allegation 1: Management has failed to properly train SPS employees and provide cleaning instructions from the manufacturer.

OSC Questions: It is indicated in the report that there are 131 individual SOPs.

a. What percentage of devices and instruments processed in SPS are covered by those 131 SOPs?
b. Is the Medical Center developing, or required to develop, SOPs for any devices and instruments not currently covered by an SOP?

Response:

a. SPS has a minimum of 100 SOPs to cover individual pieces or like categories of equipment. Each piece of equipment processed by SPS has a current SOP. The SOPs are catalogued and stored on a Sharepoint site containing a link to oneSOURCE®. OneSOURCE maintains updated manufacturers' instructions for any and all SPS items, and this information is shared with employees. OneSOURCE sends weekly updates, and SOPs are revised, as needed.
b. As new equipment is received by SPS, it is not released for use until the manufacturer's instructions are converted to an SOP and placed on the Sharepoint site. Employee training and competencies are updated, as necessary, for new equipment or modification of manufacturer's instructions.

Allegation 2A: Employees' failure to properly clean dental hand pieces, washing them only with water rather than using the required enzyme cleaning solution.

OSC Questions:

a. Are the cleaning and sterilization SOPs for drill parts and low speed hand pieces the same as the other dental hand instruments discussed? If not, what are the SOPs for drill parts and low speed hand pieces?
b. There is no discussion of how SPS employees are cleaning the dental hand pieces. Please provide a description of how SPS employees are cleaning dental hand pieces and whether it complies with the SOP.

Response:

a. Dental drill parts are contained within the appropriate dental tray or cassette. The SOP (C-4) for cleaning drill parts is attached (Attachment A). Dental hand pieces are the handles that attach to drill parts. The SOP (D-5) for cleaning hand pieces is attached (Attachment A).
b. SPS employees were not observed cleaning dental equipment during the OMI site visit, although a demonstration of the correct SOP process was provided by an SPS employee.

Allegation 2B: Employees' failure to adequately stock essential supplies on cardiac crash carts.

OSC Questions:

a. Were the 30 cardiac arrest carts required by the SOP in place at the medical center?
b. The report states that OMI viewed multiple backup carts in the SPS-Logistics area – did OMI view five backup crash carts in the SPS-Logistics area, as required by the SOP?
c. The whistleblower alleged the carts were not all properly stocked with respiratory boxes, consisting of a bi-pap and ventilator. This was not addressed in the report; please make a determination on this allegation.

Response:

a. SOP No. 140, Pharmacy Service, *Cardiopulmonary resuscitation medication kit and IV solution kit replacement procedure*, states that there are 30 cardiac arrest carts maintained by SPS. It lists 25 locations where carts will be placed. The remaining 5 carts are reserve carts and may be in logistics for processing or in the logistics hallway, fully stocked and available for replacement. There is no mandate that all five replacement carts be stocked and available in logistics. Cardiac arrest carts can be pulled from other sites or logistics, as needed, to replenish the supply on a weekend or holiday.
b. OMI reported viewing four back up carts in the logistics area.
c. Cardiac arrest carts are used for immediate resuscitation. During resuscitation, airways are managed with manual ventilation; if a patient needed an advanced ventilator device, respiratory therapy would bring the device to the patient after the resuscitation. There is no requirement to stock cardiac arrest carts with a bi-pap machine and/or ventilator.

Additional issue 2: The whistleblower alleges that SPS employees frequently fail to place sterilization indicators in peel pouches and sterilization locks on OR trays, and are mislabeling the number of instruments in sets, which requires those items to be reprocessed. On one occasion in 2011, the missing sterilization lock on an OR tray was not discovered until it was about to be opened in the OR.

OSC questions:

a. How have employees been held accountable for mistakes made in labeling and packaging? If so, how?
b. The whistleblower alleges that many mistakes are made because SPS employees are talking on or looking at personal cell phones while processing RMI; please address this allegation.
c. Please clarify whether "44 incidents where a surgical procedure was delayed or cancelled because of a problem originating with SPS" is statistically significant as compared to other similarly-sized VA facilities.
d. The whistleblower questions why OMI only reviewed the Medical Center's postoperative sepsis rate, but not the rate for communicable diseases or death, which could potentially result from negligence in SPS. Please provide clarification on why only the sepsis rate was reviewed.

Response:

a. Employees are held accountable for mistakes made in labeling and packaging. Efforts are made to improve performance and modify behaviors through re-education, verbal counseling, temporary reassignment, and remedial education.
b. OMI did not observe SPS employees using their personal cell phones while processing RME.
c. OMI reviewed 154 Close Call reports, involving SPS that were submitted to the Patient Safety Manager from March 2010 through September 2013. OMI found 44 incidents where the surgical procedure was either delayed or cancelled because of a problem originating within SPS. By comparison, the Medical Center reports that between October 2011 and December 2013, there were 18,242 surgical procedures performed; many of these procedures involving SPS processed supplies. OMI is not aware of national data for comparison of surgical delays or cancellations due to problems originating in SPS.
d. Close call reports did not reveal any events where improperly processed instruments were used on a patient during a surgical procedure. Postoperative infection rates are an acceptable way to track or discover problems with surgical technique or sterile processing. OMI requested information from the Medical Center for any incidents reported in the ORs from 2010 through 2013, that involved blood borne pathogen exposure related to dirty SPS instruments. Blood borne pathogen exposure includes communicable diseases. There were no patient incidents reported in the operating room from 2010 through 2013 that involved blood borne pathogen exposure related to dirty SPS instruments.

Attachment A

VAWNYHS STANDARD Operating Procedure: Reusable Medical Equipment D-5
Equipment: Handpieces Manufacturer: Kavo Model #(s): ALL
Section 1: General Maintenance: By Department Owning Equipment
Step 1. Clean Handpiece Cages to be delivered from SPS to the Clean Room - 131B.
Step 2. Take Handpiece Cages for each days use.(from the right side of shelf - to insure proper rotation) to the operatory.
Step 3. Store the Handpiece Cages in closed cabinet till used.(any unused cages should be returned to 131B at the end of the day).
Step 4. Open proper cassette as needed.
Step 5. Inspect Handpiece Cages and contents, for replacement/repair with each use.
Section 2: User Debridement
Step 1. Using appropriate personal protective equipment.
Step 2. Remove any bur from Handpieces. Place burs in the sharps container.
Step 3. Return all handpiece components to Cage, place in bio-bag.
Step 4. Remove gloves & close bag, take to Soiled Utility Room (122B).
Step 5. Put gloves on. Remove cage from bag, place bag in garbage.
Step 6. The cage will be placed in appropriate bin for SPS pick up.
Section 3: High Level Disinfection or Sterilization (Performed in SPS)
Step 1. Using appropriate personal protective equipment.
Step 2. Open cage, remove debris from Handpieces using a sponge or gauze under running water.
Step 3. All components will be thoroughly dried & placed in a cage.
Step 4. All components of the electric handpieces & High Speed (non-electric) will be ran in the QUATTROcare Unit as per manufacturer's instructions.
Step 5. Remove from QUATTROcare Unit dry to remove excess oil replace into Cage.
Step 6. Place in peel pouch, seal .
Step 7. Autoclave with a triple pre-vacuum @134°C +/- 1°C (273°F +/-1°F) for at least 4 minutes .
Approvals: Manager SPS: Department Manager:
Reference: 2006 Kavon Instructions for use 906.8046/4.06
Date of Development : 7/14/10 Review/Revised Date: 1/12

KH Aug 2009

VAWNYHS STANDARD Operating Procedure: Reusable Medical Equipment C-4
Equipment: Mini Instrument Cassettes -
Including ORAL SURGERY TRAYS; IMPLANT SURGICAL TRAYS; SUTURE KITS; EXAM CASSETTES; PROPHY CASSETTES;IMPLANT PROPHY CASSETTES; RESTORATIVE CASSETTES; V-RING CASSETTES; ENDODONTIC CASSETTES;RUBBER DAM CASSETTES;PROSTHETIC CASSETTES;PERIOSURGICAL CASSETTES;APICAL CASSETTES; AND ALL INSTRUMENTS CONTAINED THERE IN.
Manufacturer: Hu-Friedy
Model #'s: All
Section 1: Precleaning: Performed at Point of Use
Step 1. Using appropriate personal protective equipment.
Step 2. Remove dental materials (inorganic materials) from the cassette.
Step 3. Place the cassette in a bio-bag with gloved hand.
Step 4. Remove gloves & close the bag. Take to the Soiled Utility room (1228).
Step 5. Put glove on, Remove cassette from bag, place bag in garbage.
Step 6. Open cassette, check for damaged or missing instruments. Replace any instrument as needed.
Step 7. Remove dental debris (inorganic materials) from dental instruments with a gauze or bur brush, return dental instruments to the cassette in proper order.
Step 8. Close cassette and place in appropriate covered bin for SPS pick up.
Section 2: Cleaning (in SPS Decontamination Area)
Step 1. Place in Ultra Sonic Cleaner for a minimum of 16 min. using Ph Neutral (enzymatic) Cleaners.
Step 2. After ultrasonic cleaning, rinse cassette thoroughly with demineralized water to remove detergent or particles.
Step 3. Clean by washer/disinfector using a Ph Neutral Cleaner.
Section 3: Sterilization (Performed in SPS)
Step 1. Open the cassette and inspect instruments, making sure all debris has been removed from the instruments and cassette.
Step 2. Instruments should be dry before they are wrapped or sterilized to help prevent wet packing.
Step 3. Wrap cassette with autoclavable wrap, with the appropriate integrator.
Step 4. Autoclave at 273°F(134°C) for at least 5 min. - or- at 250°F(134°C) for 20 min.
Approvals:Manager SPS: **Department Manager:**
Date of Development: 6/23/11 **Review/Revise: 6/11/12, 6/19/2013**
Manufacturer's User Manual - Recommended IMS Processing Methods - Hu-Friedy - C6375/G9