DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

September 26, 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-13-2133

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Veterans Affairs Ann Arbor Healthcare System (hereafter, the Medical Center) in Ann Arbor, Michigan. The whistleblower alleged that the Medical Center's Supply, Processing, and Distribution (SPD) facility is inadequate for its purpose, that its physical limitations pose contamination hazards, and that members of its staff regularly violate SPD procedures, resulting in conduct that may constitute a violation of law, rule, or regulation, an abuse of authority, and a substantial and 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 substantiated one of the whistleblower's four allegations but did not substantiate the other three. It also partially substantiated 1 of 11 specific incidents the whistleblower identified in his letter to the Office of Special Counsel; it did not substantiate 1 incident and could not substantiate the remaining 9. OMI made 11 recommendations for the Medical Center and 1 for the Veterans Health Administration. 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-13-2133

Veterans Affairs
Ann Arbor Healthcare System
Ann Arbor, Michigan

Veterans Health Administration
Washington, DC

Report Date: July 24, 2013
TRIM 2013-D-760

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 (OSC) concerning the Veterans Affairs (VA) Ann Arbor Healthcare System (hereafter, the Medical Center) by (b) (6) (hereafter, the whistleblower). The whistleblower, a technician in the Logistics Service, 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 June 25-26, 2013.

The whistleblower alleged that:

1. The Medical Center's Supply, Processing, and Distribution (SPD) facility is inadequate to appropriately process, sterilize, store, and transport medical and surgical equipment.

2. Due to the facility's space and logistical restrictions, sterile supplies are not stored in an aseptic environment, entrances and exits to sterile storage are not properly controlled, and the area is too small to meet appropriate storage requirements.

3. Employees are not properly trained in safety and conduct requirements and regularly violate SPD procedures that are designed to protect against contamination of sterile supplies and equipment.

4. Design, training, and enforcement deficiencies create a risk of infection to both patients and staff.

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

1. OMI did not substantiate the allegation that the Medical Center's Sterile Processing Service (SPS) and Material Support Division (MSD) areas are inadequate to appropriately process, sterilize, store, and transport medical and surgical equipment. There is no evidence that the current space limitations have limited the Medical Center's ability to provide quality care in a safe and effective manner. However, the Medical Center has recognized the need for expansion to improve function and has an approved renovation plan with funding pending.

2. OMI noted that most sterile trays were segregated on shelves in the center of the room; however, we observed some non-sterile items stored both above and next to sterile items.

3. OMI did not substantiate the allegation that entrances and exits to sterile storage are not properly controlled.

4. OMI did not substantiate the allegation that the storage area is too small to meet the appropriate requirements; however, the storage area is very congested, and the renovation will reduce congestion.

5. OMI substantiated the allegation that employees are not properly trained in safety and conduct requirements and violate procedures that are designed to protect against contamination of sterile supplies and equipment although there is no evidence of contamination resulting from noncompliance by staff.

6. The different dress codes for SPS and MSD staff who work within the same area are confusing. Utilizing the same coverups for different functions makes both training and compliance monitoring difficult.

7. The availability of a door with direct access to the decontamination area from the locker and rest rooms enables an improper traffic flow.

8. The Environmental Management Service (EMS) staff supporting the SPS and MSD areas was not adequately trained.

9. On one occasion, the whistleblower did not respond appropriately to remove items he felt were contaminated from the supply chain although he did notify his union representative. These items were removed by the Assistant Chief of SPS.

10. There is no evidence of an increase in medical equipment-related infections; therefore, OMI did not substantiate the allegation that design, training, and enforcement increased the risk of infections in either staff or patients.

11. Of the 11 specific incidents related to the allegations that the whistleblower identified in his letter to OSC, OMI partially substantiated 1, did not substantiate 1, and could not substantiate the remaining 9.

Recommendations

The Medical Center should:

1. Provide additional training for MSD staff on stocking shelves in supply storage. This training should include a review of relevant Medical Center Standard Operating Procedures and Association for the Advancement of Medical Instrumentation, Association of peri-Operative Registered Nurses, and Association for Professionals

in Infection Control and Epidemiology standards regarding storage of clean and sterilized supplies. Once training has been completed, monitor compliance and address noncompliance.

2. While awaiting funding for its approved renovations, reorganize storage in the supply storage room to ensure that all sterile supplies and equipment are segregated from non-sterile supplies.

3. Re-evaluate and rewrite the Medical Center's dress policies for restricted areas to decrease confusion, and to simplify training, enforcement, and monitoring.

4. Provide training to SPS and MSD staff on the revised dress policy. Once training is completed, monitor compliance and address noncompliance.

5. Retrain decontamination staff members on traffic flow in their section and on appropriate use and discarding of personal protective equipment. Once training is completed, monitor compliance and address noncompliance.

6. Ensure appropriate placement of trash receptacles at the decontamination area's exits, and monitor compliance with its use.

7. Consider sealing the door between the decontamination area and the room outside the locker and restrooms to eliminate the temptation to inappropriately utilize this door.

8. Consider making the door from the decontamination area into the clean corridor one-way and realigning functions so that employees from the clean supply storage staff are responsible for retrieving the clean carts from the washer for use in preparing case carts.

9. Provide training on proper cleaning methods in the SPS and MSD areas to the EMS Supervisor and EMS staff responsible for cleaning these areas. Once training is completed, monitor compliance and address noncompliance.

10. Provide MSD staff training on removal of suspected contaminated supplies. Once training is completed, monitor compliance and address noncompliance.

11. Provide training for MSD staff on removing soiled supplies from carts. Once training is completed, monitor compliance and address noncompliance.

The Veterans Health Administration should:

12. Consider accelerating funding of the Medical Center's approved SPS and MSD renovation plan to ensure that these services continue to expand to meet growing demand.

Summary Statement

OMI's investigation and review of its findings did not find violations or apparent violations of statutory laws, mandatory rules, or regulations.

I. Introduction

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Veterans Affairs (VA) Ann Arbor Healthcare System (hereafter, the Medical Center) by (b) (6) (hereafter, the whistleblower). The whistleblower, a medical supply technician in the Material Support Division (MSD) of the Logistics Service, 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 June 25-26, 2013.

II. Facility Profile

The VA Ann Arbor Healthcare System consists of the Medical Center and three community-based outpatient clinics. The Medical Center is a tertiary care facility and provides a full range of patient care services, including medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, dentistry, geriatrics, and extended care. Comprised of 105 inpatient beds and 46 community living center beds, the Medical Center maintained an average daily census of 87, had an 82.9 percent occupancy rate, had 504,542 outpatient visits, and performed 4,918 surgical procedures during fiscal year (FY) 2012.

The Medical Center has active medical school affiliations with the University of Michigan Medical School and the University of Toledo College of Medicine. Over 800 University of Michigan residents and students train at the Medical Center each year. There are also nursing student affiliations with the University of Michigan, University of Toledo, Eastern Michigan University, Madonna University, and Washtenaw Community College as well as affiliations with the University of Michigan in dentistry, dental hygiene, pharmacy, social work, psychology, and physical therapy. Overall, the Medical Center has over 85 affiliations and supports a health services research and development program and a Geriatric Research, Education, and Clinical Center.

III. Conduct of Investigation

An OMI team consisting of (b) (6) M.D., Deputy Medical Inspector for Professional Services (a surgeon); (b) (6) R.N., Clinical Program Manager; and (b) (6) Health Systems Specialist, Veterans Health Administration (VHA) National Program Office for Sterile Processing, conducted the investigation. OMI reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. OMI toured the Sterile Processing Service (SPS) and MSD area during the dayshift (announced) and during the evening shift (unannounced). An entrance and an exit briefing were held with the Medical Center leadership.

The whistleblower was interviewed telephonically prior to the OMI site visit and in person during the site visit; at the latter, he was accompanied by (b) (6) a representative of the American Federation of Government Employees, Local 2092. OMI also interviewed the following individuals: (b) (6) Chief, Logistics; (b) (6) (b) (6) Logistics, MSD Supervisor; (b) (6) (b) (6) (former SPS lead), (b) (6) (b) (6) MSD staff; (b) (6) Chief SPS; (b) (6) (b) (6) SPS staff; (b) (6) Patient Safety Manager; (b) (6) Safety Officer; (b) (6) M.D., Program Director, Infection Control; (b) (6) Infection Control Nurse; (b) (6) Associate Director, Patient Care Services (Nurse Executive); (b) (6) Environmental Management Service (EMS) Night Supervisor; and (b) (6) EMS staff.

The Office of General Counsel reviewed OMI's findings to determine whether there was any violation of law, rule, or regulation.

IV. Background

Before 2009, the Medical Center's Department of Sterile Processing and Distribution (DSPD) was responsible for receiving, storing, and distributing medical supplies as well as for decontaminating and sterilizing reusable medical supplies and equipment. The Chief, DSPD, was responsible for the management of the supply, processing, and distribution functions within the Medical Center. In 2009, VHA realigned DSPD functions to more clearly emphasize the processing of reusable medical equipment. Per VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organization Structure and Reprocessing Requirement, the portion of DSPD responsible for processing was reassigned to the Associate Director, Patient Care Services (Nurse Executive); this service was renamed the Sterile Processing Service (SPS) to reflect the change in its function. The distribution function of DSPD was reassigned to the Logistics Service and named MSD. Employees in the former DSPD were reassigned to either SPS or MSD based on the area where they principally worked prior to the realignment.

In 2010, the Medical Center recognized the growing requirements for sterile supply due to increased productivity in the operating room (OR) and initiated plans to expand and renovate the SPS area. Over the past 5 years, the number of surgeries performed at the Medical Center has steadily increased from 3,921 in FY 2008; 4,662 in FY 2011; 4,918 in FY 2012; and a projected 4,644 in FY 2013. Given the expanding needs of the section, the scope of the project was broadened and new designs submitted in August 2012. The final plan includes additional storage space, locker room space, processing space, and additional processing equipment. The final plan has been approved by the National Program Office for Sterile Processing and submitted to VA for funding.

In order to ensure the cleanliness and sterility of inventory processed and stored in the SPS and MSD areas, staff must adhere to specific standards. These standards include

those noted in Handbook 1761.02, VHA Inventory Management; the VHA Design Guide for Supply, Processing and Distribution; the Medical Center Standard Operating Procedures (SOP), Environmental Control of Storage Area, and Inventory Distribution; and standards developed by the Association for the Advancement of Medical Instrumentation (AAMI), the Association of peri-Operative Registered Nurses (AORN), and the Association for Professionals in Infection Control and Epidemiology (APIC). Per the Medical Center's SOP, AAMI, and APIC standards, storage areas are designated as clean or dirty. Sterile materials should be stored in a clean environment. The lower shelves in the storage areas should be solid and with at least 8 inches of space between the floor and bottom shelf to allow for proper cleaning under the shelving unit while avoiding contamination of medical supplies. Top shelves and contents will be arranged 18 inches from fire detection or extinguishing systems that are installed in, or suspended from, the ceiling. Shelving must be at least 2 inches from outside walls to avoid condensation and contamination of supplies. The items should be positioned so that packages are not crushed, bent, compressed, or punctured, so their sterility is not compromised. Medical and surgical supplies should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet. Storage of supplies on floors, window sills, and areas other than designated shelving, counters, or carts should be avoided.[1] Cartons and corrugated boxes used to ship supplies from the manufacturer or warehouse should not be taken into the clean/sterile areas of SPS and MSD.

V. Allegations

The whistleblower alleged that:

1. The Medical Center's Supply, Processing, and Distribution (SPD) facility is inadequate to process, sterilize, store, and transport medical and surgical equipment appropriately.

2. Due to the facility's space and logistical restrictions, sterile supplies are not stored in an aseptic environment, entrances and exits to sterile storage are not properly controlled, and the area is too small to meet the appropriate storage requirements.

3. Employees are not properly trained in safety and conduct requirements and regularly violate SPS procedures that are designed to protect against contamination of sterile supplies and equipment.

4. Design, training, and enforcement deficiencies create a risk of infection to both patients and staff.

[1] AAMI: www.aami.org/publications/standards; APIC: www.apic.org/professional-practice

VI. Findings

Currently, SPS and MSD are collocated at the Medical Center, reflecting the organizational structure prior to 2009; the floor plan is shown in Attachment B. The physical layout includes designated "clean" areas for storage of sterile and nonsterile supplies, bulk storage, and assembly (where clean instruments are packaged and sterilized); additional areas designated "dirty" for decontamination (where dirty supplies and instruments are washed and disinfected); "breakout" (where supplies are removed from boxes and packaging); and "preparation and assembly" (where the final processing of sterile medical supplies, instruments, and equipment takes place). There are also offices, male and female locker rooms and restrooms, and a break room.

Several staff members voiced unhappiness with their assignment to Logistics Service at the time of the realignment. In addition, they reported that a lack of permanent leadership in MSD for several years interfered with their training. The current leadership of MSD has developed a training schedule, and new staff that we interviewed reported awareness of and participation in the training.

The MSD's current area for supplies is one very large room in which both sterile and nonsterile supplies are stored. Although the room was very full, all supplies were on shelving and met the storage requirements noted above. Bulk storage, a room adjacent to the supply storage room, also met all requirements noted above. The OR case carts are prepared in another area next to this room.[2]

The decontamination area is a separate room where dirty instruments and equipment are processed and prepared for cleaning. Because it is considered dirty, all staff entering this area are required to wear the appropriate personal protective equipment (PPE). Dirty case carts from the OR are transported directly to the decontamination area via an electric lift labeled "Dirty." After the contents are removed, each cart is placed in an automatic washer that cleans and dries it. Cleaned carts exit the washer through a separate door leading to a clean corridor that connects to the supply storage room.

The cleaning of instruments includes inspection for gross soiling, opening and positioning for "complete cleaning," and grouping of instruments based on their composition (metal vs. plastic). OMI observed adequate sinks and ultrasonic devices for cleaning. Equipment and instruments are placed in automatic washers for cleaning and drying. These washers are located in the wall separating the decontamination area from the preparation and assembly area. There is no door connecting the two areas, and staff have to walk through both the sterile and nonsterile storage environments to enter the SPS. The washers are loaded on the decontamination area side, and once the cleaning cycle finishes, the contents are automatically ejected onto a conveyor belt to dry. They are then unloaded from the conveyor belt by staff in the preparation and assembly area. To prevent cross contamination, the washer doors in the

[2] The case cart is a closed cabinet in which supplies and instruments for a specific case are placed for transport to the OR. The content of the carts is based on the type of surgery planned and the surgeon's specific preference card.

decontamination area will not open if the doors on the preparation and assembly side are open, and vice versa. The preparation and assembly area is where the final processing of sterile medical supplies, instruments, and equipment takes place. After removing items from the washer units, the staff packages and sterilizes them. Items are then placed in trays that are double-wrapped and secured with both internal and external labels that verify the sterility of the contents. Once the items have been processed and prepared for use, they are delivered to MSD for distribution.

The breakout room is the area where the MSD staff unpack new supplies and equipment from their transport packaging; it is not a clean area. The boxes are brought into the room, and the contents removed by the MSD staff. Once unpacked, the boxes are broken down and discarded. Opening and removing contents from these boxes can generate dust and debris. In this area, MSD staff are required to wear scrub suits covered by short length, long-sleeved warmup jackets, which they also wear into the supply storage room.

The offices, locker rooms, restrooms, and break room are considered common areas in which street clothes are allowed. During his interview, the whistleblower voiced a concern that the former MSD men's locker room had been reconfigured into the break room, requiring male staff to share the locker room closer to the decontamination room. This locker room was found to be well-maintained with a regular EMS cleaning schedule. After employees working in the decontamination area remove their PPE prior to leaving the room, they are not contaminated as implied by the whistleblower. The Medical Center reconfigured the break room on the other side of the SPS section in response to drink cans being found in the decontamination area – an area where eating and drinking are not allowed.

In the processing and storage areas of SPS and MSD, the Medical Center controls the temperature, humidity, and air flow to minimize the movement of microorganisms from dirty areas to clean areas, thus decreasing the likelihood of contamination of clean supplies and equipment. Positive air flow must be maintained in the clean areas, and negative air flow maintained in the dirty areas. As stipulated in VA Central Office Memorandum, Interim Guidance for Ventilation Requirement for Sterile Processing Service, issued by the Assistant Deputy Under Secretary for Health for Clinical Operations, and AAMI standards, the clean areas must have a minimum of 10 air exchanges per hour, and dirty areas a minimum of 6 exchanges per hour.[3] According to documentation provided by the Medical Center, the temperature and humidity reports are within standards, and the air exchanges in the clean and dirty areas are at or above the required minimum number per hour.

The entrances to the SPS and MSD areas are restricted by key access. There is restricted dress for both SPS and MSD staff within each section. In the supply storage area, the SPS staff wore scrub suits and head, hair, and shoe covers. The MSD staff wore scrub suits covered by short, darker-colored warmup jackets.

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[3] AAMI: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2006 and ANSI/AAMI/A1:2008/A2:2009.

AORN recommends storing sterile and clean supplies separately.[4] If sterile items are stored in the same area with nonsterile supplies, they should be stored on separate shelves and above the nonsterile supplies. Because the Medical Center currently has limited storage space pending the approved renovation, its storage room was very full; MSD was using all available space, including an enclosed corridor, in its section to store supplies. Most sterile trays were segregated on shelves in the center of the room. OMI observed nonsterile items stored both above and next to sterile items, i.e., a sterile chest tube kit stored next to a box of clean gloves and a sterile orthopedic surgical tray stored next to clean, nonsterile supplies. When asked, staff stated these items are stored by service resulting in both sterile and nonsterile supplies on the same shelf. No supplies were noted to be stored outside of the SPS or MSD area.

During the tour of SPS and MSD areas, OMI was appropriately instructed to put on the PPE in the secured entry corridor prior to entering the bulk storage area. The attire consisted of head, hair, and shoe covers and a long cover gown; we noted this was the same type of long cover gown the SPS staff wears when leaving the area to go elsewhere in the Medical Center.

The anteroom just outside the entrance to the decontamination area serves as the place where staff put on their PPE before entering. OMI observed staff exiting the decontamination area still wearing their PPE, which should have been removed in the decontamination area, but it lacked a PPE disposal container at the exit. OMI observed one staff member remove her PPE in the decontamination area, drop it on the floor, and leave to go to the bathroom.

No staff wearing decontamination area PPE were observed unloading clean instruments from the preparation and assembly side, and all staff working in the decontamination area were observed wearing PPE.

Cleaned case carts exit the washer in a corridor directly adjacent to the decontamination area. Some cleaning supplies and brushes are also stored in this corridor. One staff member assigned to the decontamination area admitted to entering the clean corridor wearing her decontamination PPE to "quickly grab some brushes for cleaning decontaminated items." She did report that she had been trained to remove her PPE when leaving the decontamination area.

The decontamination area has a door into the room that connects to the male and female locker and restrooms. Although management indicated this door should not be used as an entrance, several staff reported using the door to go in and out of the decontamination room. There is no signage indicating staff should not use this door as a passageway, and the door is not locked from either side. One staff member in the decontamination area reported utilizing this door to go to the restroom because it is "quicker than going out through the anteroom," which is the required procedure. In addition, another decontamination area staff member reported using the door to step

[4] AORN standard http://www.aornjournal.org/article/S0001-2092(11)00473-X/fulltext.

into the decontamination area in his street clothes to send the dirty elevator back to the OR as it was sounding an alarm. Both he and his supervisor reported he was reprimanded for this action.

During the tour, staff was observed leaving the breakout room in scrub suits covered by warmup jackets and entering the clean/sterile storage area in the same attire. When asked about the dress policy for the SPS and MSD areas, the staff gave different answers even though they worked in the same shared locations. The Logistics Supervisor stated that staff is not required to wear cover gowns outside of sterile/nonsterile storage although dust and debris are generated in the breakout area. The supervisor stated this practice is based on the protocol followed in the OR. The OR Nurse Manager confirmed that staff is no longer required to wear cover gowns over their scrub suits when leaving the OR to travel to other areas within the Medical Center as long as they stay inside the building. They are also not required to change uncovered scrub suits when returning to the OR area. She stated the OR instituted this practice between 2003 and 2004 based on an interpretation of the following AORN standards: the AORN periOperative Standards Recommended Practices for Surgical Attire, recommendation II f1 states, "the use of cover apparel has been found to have little or no effect on reducing contamination of surgical attire." The supporting documentation for this recommendation refers to cover apparel that is not discarded on a daily basis, not laundered daily, or is home-laundered.

The MSD section assembles the case carts then distributes the carts to the OR via a clean electric lift. The whistleblower alleged that MSD staff are not familiar with the instruments and have difficulty finding an instrument when requested by the OR. Two MSD staff interviewed stated that they could benefit from additional training about the instruments, but they reported no problems seeking out staff in the preparation area for assistance with instrument identification when special requests are made outside of the equipment already on the case carts. All SPS and some MSD staff have completed SPS Level 1 basic training about processing and preparation within the SPS area. The Medical Center has recently instituted a requirement for SPS Level 1 training for all MSD staff. During FY 2012, no surgical cases were reported as delayed or cancelled because of SPS or MSD training issues.

The SPS and MSD areas are cleaned during the night shift. The cleaning schedule includes a daily list of tasks to be completed. When interviewed, the supervisor for the EMS staff responsible for cleaning these areas was not able to articulate the cleaning process, what equipment should be used to clean in these areas, what solutions should be used for cleaning these areas, or the specific solution viscosity requirements to limit splashing.

The whistleblower alleges that he noticed splashes of a liquid on a supply cart and some supplies located on lower shelves after the area was cleaned. He did not remove these supplies from the cart, nor did he notify his supervisor. Instead, he contacted his union representative with his observations. The Assistant Chief of SPS reported that, after notification, she verified that the supply packaging was stained with splash marks

and removed the affected items, discarding the disposable items and sending the reusable items for reprocessing.

VA Surgical Quality Improvement Program

The Medical Center submits data on the rates of morbidity and mortality in Veterans undergoing surgical procedures within the OR; this 38 United States Code § 5705, "Confidentiality of medical quality-assurance records protected quality improvement information", is submitted to the VA National Surgery Office for analysis in the VA Surgical Quality Improvement Program (VASQIP) on a quarterly basis.[5] Review of their VASQIP data for FY 2012 revealed no evidence of morbidity and mortality rates higher than expected when compared to similar VA medical centers. Review of the Medical Center's Infection Control Committee meeting minutes did not reveal evidence of elevated infection rates in patients who underwent surgical procedures. No incidents of infection or other adverse outcomes in patients or staff have been linked to instrument processing, storage, or distribution.

OMI was unable to find any evidence that the current design, training, and enforcement increased the risk of infection to either patients or staff. In addition, sterile processing includes two sterility indicators, both internal and external, to validate appropriate sterility and to provide a check of the process. SPS runs periodic controls to test the validity of their processes, and all tests confirm processes are within policy; therefore, there is no evidence that improperly processed instruments ever reached an end user.

As part of its quality improvement program, the Medical Center elicits and monitors feedback from end users of the equipment. The OR reports on the quality of instrument processing, timeliness, and availability of instruments and proper assembly of the different trays. During the current fiscal year, the OR reported 78 incidents of receiving trays with missing, wrong, or damaged instruments; the monthly average for these incidents has decreased from approximately 14 per month to 2 per month. The number of incidents of improperly assembled trays was reported as 61 for the current fiscal year; the monthly average for these incidents has decreased from approximately 13 per month to approximately 4 per month. No OR cases were reported delayed or canceled because of SPS or MSD issues.

OMI was unable to find any evidence that the current design, training, and enforcement increased infection to either patients or staff. In addition, sterile processing includes two sterility indicators, both internal and external, to validate appropriate sterility and provide a check of the process. SPS runs periodic controls to test the validity of their processes, and all tests confirm processes are within policy; therefore, there is no evidence that improperly processed instruments ever reached an end user.

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[5] The VASQIP system is used to create reports regarding quality of the surgical care given to VA patients. VASQIP analyzes major surgical procedures with detailed clinical preoperative risk and procedural and outcomes data. VASQIP identifies the range of statistically acceptable outcome rates for mortality and morbidity for overall and specialty surgical procedures performed and assessed by any one facility.

VII. Specific Incidents Related to the Allegations

Incident 1: 2/25/13: (b) (6) a new supply technician, was lifting surgical trays by the lids and not the handles, causing instruments inside to become contaminated.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee denies that this occurred. In addition, the SPS and OR staff interviewed stated that even if the tray is lifted by its lid, without evidence of disruption of the external indicator, the set is not compromised. If the sterility was compromised, an external indicator sterility tab would break. OMI attempted to compromise the sterility of a tray by lifting it by the lid but was unable to break the external indicator without actively opening the storage tray. This would have resulted in the disruption of the external indicator that would alert an end user to a compromise of sterility.

Incident 2: 1/1/13: (b) (6) GS-6, worked in the decontamination in his street clothes. He entered sterile storage area several times through the decontamination hallway in his street clothes.

OMI substantiated that a portion of this incident occurred. Mr. (b) (6) admitted to entering the decontamination area in his street clothes through the door to the room adjacent to the locker and restrooms to address an alarm on the dirty elevator. The individual states he did this only once and was immediately counseled by his team leader; this incident was confirmed by the team leader.

Incident 3: 12/29-12/30/12: (b) (6) worked in decontamination in street clothes. He entered sterile supply/storage many times during the weekend in his street clothes.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee denied working in his street clothes on the days indicated.

Incident 4: 12/30/12: (b) (6) GS-6, entered sterile supply/storage through the decontamination hallway doors carrying food under the long blue gown she had draped over her food.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee denied carrying food through the decontamination hallway under a blue gown.

Incident 5: 10/3/12, 12/1/12, 12/2/12, 12/15/12: (b) (6) worked in decontamination in his street clothes. He entered sterile storage many times during the weekend in his contaminated street clothes through the decontamination hallway. He also came into sterile supply in his street clothes through the decontamination area.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee denied working in his street clothes. In addition, the whistleblower's

reference to the decontamination hallway reflects some confusion on his part about this clean corridor.

Incident 6: 12/15/12: The whistleblower entered sterile storage, and the doors between the decontamination hallway and sterile storage were propped open.

OMI could not substantiate this incident. No other staff witnessed this incident. The hallway outside of the decontamination area is considered clean; however, OMI did not see air exchange reports for this area of the section to ascertain whether it was a positive or negative airflow.

Incident 7: 12/13/12: (b) (6) GS-9, entered sterile supply in a contaminated blue jacket. She did not wear a cover gown when outside the sterile storage.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee had no recollection of this date. Additionally, the MSD current policy allows the wearing of the blue jacket outside of the SPS/MSD area as long as the employee does not leave the building.

Incident 8: 12/2/12: (b) (6) entered sterile storage through the decontamination hall doors and continued through into sterile preparation.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee denied entering sterile storage through the decontamination hallway and continuing through into sterile preparation. Again, the corridor outside of decontamination is a clean area.

Incident 9: 10/2/12: (b) (6) Nurse II, and (b) (6) GS-7, were giving a tour of sterile storage and SPS preparation to four individuals, and the individuals were not properly attired and were not wearing shoe covers.

OMI did not substantiate this incident. (b) (6) and others present during this tour stated the four individuals were attired appropriately.

Incident 10: 10/27/12: During the weekend, (b) (6), GS-6, was working in decontamination and was in and out of sterile supply/preparation in contaminated scrubs. The whistleblower observed him not dressed in PPE while cleaning trays and equipment.

OMI could not substantiate this incident. No other staff witnessed this incident. The employee denied that this occurred.

Incident 11: 10/29/12: (b) (6) GS-7, entered sterile storage through the breakout room doors and was not properly attired.

OMI could not substantiate this allegation. No other staff witnessed this incident. The employee was not available to interview.

VIII. Conclusions

1. OMI did not substantiate the allegation that the Medical Center's SPS and MSD areas are inadequate to appropriately process, sterilize, store, and transport medical and surgical equipment. There is no evidence that the current space limitations have limited the Medical Center's ability to provide quality care in a safe and effective manner. However, the Medical Center has recognized the need for expansion to improve function and has an approved renovation plan with funding pending.

2. OMI noted that most sterile trays were segregated on shelves in the center of the room; however, we observed some nonsterile items stored both above and next to sterile items.

3. OMI did not substantiate the allegation that entrances and exits to sterile storage are not properly controlled.

4. OMI did not substantiate the allegation that the storage area is too small to meet the appropriate requirements; however, the storage area is very congested, and the renovation will reduce congestion.

5. OMI substantiated the allegation that employees are not properly trained in safety and conduct requirements and violate procedures that are designed to protect against contamination of sterile supplies and equipment although there is no evidence of contamination resulting from noncompliance by staff.

6. The different dress codes for SPS and MSD staff who work within the same area are confusing. Utilizing the same coverups for different functions makes both training and compliance monitoring difficult.

7. The availability of a door with direct access to the decontamination area from the locker and restrooms enables an improper traffic flow.

8. The EMS staff supporting the SPS and MSD areas was not adequately trained.

9. On one occasion, the whistleblower did not respond appropriately to remove items he felt were contaminated from the supply chain although he did notify his union representative. These items were removed by the Assistant Chief of SPS.

10. There is no evidence of an increase in medical equipment-related infections; therefore, OMI did not substantiate the allegation that design, training, and enforcement increased the risk of infections in either staff or patients.

11. Of the 11 specific incidents related to the allegations that the whistleblower identified in his letter to OSC, OMI partially substantiated 1, did not substantiate 1, and could not substantiate the remaining 9.

IX. Recommendations

The Medical Center should:

1. Provide additional training for MSD staff on stocking shelves in supply storage. This training should include a review of relevant Medical Center SOPs, AAMI, AORN, and APIC standards regarding storage of clean and sterilized supplies. Once training has been completed, monitor compliance and address noncompliance.

2. While awaiting funding for its approved renovations, reorganize storage in the supply storage room to ensure that all sterile supplies and equipment are segregated from non-sterile supplies.

3. Re-evaluate and rewrite the Medical Center's dress policies for restricted areas to decrease confusion and to simplify training, enforcement, and monitoring.

4. Provide training to SPS and MSD staff on the revised dress policy. Once training is completed, monitor compliance and address noncompliance.

5. Retrain decontamination staff members on traffic flow in their section and on appropriate use and discarding of PPE. Once training is completed, monitor compliance and address noncompliance.

6. Ensure appropriate placement of trash receptacles at the decontamination area's exits, and monitor compliance with its use.

7. Consider sealing the door between the decontamination area and the room outside the locker and restrooms to eliminate the temptation to utilize inappropriately this door.

8. Consider making the door from the decontamination area into the clean corridor one-way and realigning functions so that employees from the clean supply storage staff are responsible for retrieving the clean carts from the washer for use in preparing case carts.

9. Provide training on proper cleaning methods in the SPS and MSD areas to the EMS Supervisor and EMS staff responsible for cleaning these areas. Once training is completed, monitor compliance and address noncompliance.

10. Provide MSD staff training on removal of suspected contaminated supplies. Once training is completed, monitor compliance and address noncompliance.

11. Provide training for MSD staff on removing soiled supplies from carts. Once training is completed, monitor compliance and address noncompliance.

VHA should:

12. Consider accelerating funding of the Medical Center's approved SPS and MSD renovation plan to ensure that these services continue to expand to meet the growing demand.

Attachment A

1. ANSI/AAMI Guidelines 2009.
2. AORN Perioperative Standards and Recommended Practices 2012.
3. APIC Guidelines 2012.
4. Medical Center Infection Control Committee Meeting Minutes FY 2013.
5. Medical Center SPS and MSD staff competency folders.
6. Medical Center VASQIP data FY 2012.
7. VA Ann Arbor Policy Memorandum 00-53, *Use and Reprocessing of Reusable Medical Equipment (RME).*
8. VA Ann Arbor Policy Memorandum 00-53, Attachment A-1, *Reusable Medical Equipment Retirement, Replacement and Standardization Process.*
9. VA Ann Arbor SOP- 4005, *Steam Sterilization Procedure.*
10. VA Ann Arbor SOP, May 22, 2012: *Environmental Control of Storage Areas.*
11. VA Ann Arbor SOP, May 22, 2012: *Inventory Distribution.*
12. VA Memorandum, *Interim Guidance for Ventilation Requirements in Sterile Processing Service.*
13. VA Policy Memorandum 90-25, April 16, 2013: *Dress Attire Central Supply.*
14. VHA Design Guide for Supply, Processing and Distribution, February 2010.
15. VHA Directive 2009-031, June 26, 2009: *Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structures and Reprocessing Requirements.*
16. VHA Handbook 1761.02, October 20, 2009: *VHA Inventory Management.*
17. VISN 11 Quality Assurance Report FY 2013.

Attachment B