DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420
January 21, 2016

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-15-5181

Dear Ms. Lerner:

I am responding to your August 18, 2015, letter to the Department of Veterans Affairs (VA) regarding allegations made by a whistleblower at the Southern Arizona VA Health Care System (hereafter, the Medical Center), Tucson, Arizona. The whistleblower alleged that Medical Center employees may have engaged in conduct that may constitute violations of laws, rules or regulations, gross mismanagement, and a substantial and specific danger to public health. Specifically, the whistleblower alleged that the Sterile Processing Service of the Medical Center failed to properly handle reusable medical equipment (RME). The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as described in 5 United States Code § 1213(d)(5).

The Under Secretary for Health directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. VA did not substantiate the first two allegations, partially substantiated the third, and was unable to substantiate the fourth. VA made six recommendations to the Medical Center and two to the Veterans Health Administration (VHA). Findings from the investigation are contained in the enclosed report, which I am submitting for your review. I have reviewed these findings and agree with the recommendations in the report. We will send your office follow-up information describing actions that have been taken by the Medical Center and VHA to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,

Robert D. Snyder
Interim Chief of Staff

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Report to the
Office of Special Counsel
OSC File Number DI-15-5181

Department of Veterans Affairs
Southern Arizona VA Health Care System
Tucson, Arizona

Report Date: December 7, 2015

TRIM 2015-D-5606

Executive Summary

The Under Secretary for Health (USH) directed that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Southern Arizona VA Health Care System, (hereafter, the Medical Center) located in Tucson, Arizona. Whistleblower (hereafter, the whistleblower), who consented to the release of her name, alleged that employees in Sterile Processing Service (SPS) consistently fail to follow proper procedure in decontaminating, cleaning, sterilizing, packaging, storing, and distributing reusable medical equipment (RME), and 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. The VA team conducted a site visit to the Medical Center on August 31, 2015, to September 4, 2015.

Specific Allegations of the Whistleblower

1. Sterile Processing staff does not perform decontamination, cleaning, sterilization, packaging, storing, and distribution of medical and surgical device processes in accordance with competencies established by device manufacturers and VA procedures, thus increasing the possibility of contamination.

2. Sterile Processing managers emphasize speed over compliance with the competencies.

3. Sterile Processing is grossly understaffed and does not have the manpower to meet the decontamination, cleaning, sterilization, and packaging competencies.

4. Sterile Processing managers falsify official Government documents regarding education and training of medical supply technicians in order to satisfy VA record keeping requirements and pass periodic inspections.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions for Allegation 1

- VA **does not substantiate** the allegation that SPS staff does not perform decontamination, cleaning, sterilization, packaging, storing, and distribution of medical and surgical device processes in accordance with competencies established

by device manufacturers and VA procedures, thus increasing the possibility of contamination.

- VA found written evidence of SPS leadership enforcing standard operating procedures (SOP) and VHA Directives. This is the most comprehensive SOP and competency training program seen by this VA team.

- The Medical Center staff has an engaged quality assurance program that is responsive to periodic rate changes as evidenced by the downward trend in the VA Surgical Quality Improvement Program (VASQIP) reported rates over the last 3 years.

- VA identified one example of initial poor communication between the operating room (OR) staff and SPS related to procuring a new surgical instrument which added undue stress to SPS personnel who were trying to meet operating room needs.

- The national requirement that the Medical Center SPS leadership develop extremely detailed SOPs and competencies for each individual piece of RME, a duplication of the manufacturers' instructions for use (IFU), is a labor-intensive process, and the management of this process is extremely cumbersome at a busy Level 1 facility.

Recommendations to the Medical Center

1. Develop a protocol for the OR to immediately notify SPS when an RME is acquired from outside vendors, to facilitate a smoother and less urgent response for SPS processing.

Recommendation to VHA

1. Review the requirements that mandate writing SOPs on each individual piece of RME, to determine how to make the competency assessment process more efficient.

2. As recommended in OSC File Number DI-15-2103, VHA should publish a handbook to address the specific SPS portions of VA Directive and Handbook 7176, *Supply, Processing, and Distribution,* as soon as possible.

Conclusions for Allegation 2

- VA **does not substantiate** the allegation that SPS managers emphasize speed over compliance with the competencies. VA found that SPS leadership emphasized strict compliance and efficiency with SOPs and competencies.

- VA found that there is a priority system in place to help triage workload when it exceeds immediate staffing resources, and that this system is communicated to and understood by the staff.

- Leadership's communication style and the constant workload pressure increased the SPS Technicians' level of stress.

Recommendations to the Medical Center

2. Provide training/tools on effective communication for SPS staff.

3. Consult with the National Center for Organizational Development (NCOD) or an outside consultant to implement team building for SPS staff on all tours of duty.

Conclusions for Allegation 3

- VA **substantiates** that SPS is understaffed. While we appreciated leadership's attempt to provide promotion opportunities for current employees, they have stretched the available SPS staff to the maximum.

- VA **does not substantiate** that the current manpower is not meeting competencies. Productivity and quality of instruments and trays to date have met the needs of the Medical Center; however, this has required SPS leadership to fill vacancies and is unsustainable.

Recommendations to the Medical Center

4. Fill medical supply technician vacancies as soon as possible and consider the use of temporary contract staff in SPS while new staff is brought onboard and trained.

5. Continue to monitor the SPS quality indicators (e.g., OR incident reports, CAPA forms, SCL QI forms, etc.) for trends and continue to take appropriate actions in response.

Conclusions for Allegation 4

- VA was **not able to substantiate** the allegation that SPS managers falsify official Government documents regarding education and training of medical supply technicians in order to satisfy VA record keeping requirements and pass periodic inspections.

- There is extensive evidence of ongoing training and education throughout the year, which is not associated with external inspections.

- There is a verbal report of training being completed by the Chief of SPS for a subordinate which could not be confirmed.

Recommendation to the Medical Center

6. At the direction of the investigation team, the Medical Center convened an Administrative Investigation to reconcile the contradictory testimony about a supervisor completing Talent Management System training on behalf of an employee. This investigation is underway; if evidence is found that substantiates the allegation, take appropriate administrative and disciplinary action.

Summary Statement

VA has developed this report in consultation with other Veterans Health Administration (VHA) and VA offices to address OSC's concerns that the Medical Center may have violated law, rule, or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the Office of General Counsel (OGC) has provided a legal review, VHA Human Resources (HR) has examined personnel issues to establish accountability, and the Office of Accountability Review (OAR) has reviewed the report and has or will address potential senior leadership accountability. The Medical Center's potential violation of law, rule, and regulation is being addressed by an Administrative Investigation.

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I. Introduction

The Under Secretary for Health (USH) directed that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Southern Arizona VA Health Care System, (hereafter, the Medical Center) located in Tucson, Arizona. Whistleblower (hereafter, the whistleblower), who consented to the release of her name, alleged that employees in Sterile Processing Service (SPS) consistently fail to follow proper procedure in decontaminating, cleaning, sterilizing, packaging, storing, and distributing reusable medical equipment (RME), and 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. The VA team conducted a site visit to the Medical Center on August 31, 2015, through September 4, 2015.

II. Facility Profile

The Medical Center, part of Veterans Integrated Service Network (VISN) 18, serves over 170,000 Veterans across eight counties in southern Arizona and one in western New Mexico. The Medical Center operates 285 beds, providing primary care, and subspecialty health care in numerous medical areas. It has training affiliations with over 70 academic institutions and is the principal affiliate with the University of Arizona's Colleges of Medicine, Nursing, and Pharmacy. Approximately 54,000 unique patients are seen annually, with nearly 8,000 inpatient admissions and more than 684,000 outpatient visits. It is a surgical complexity level 1A facility and has 13 operating rooms (OR).[1] The SPS area consists of: RME critical/semi-critical storage area; disposable supplies storage area (stock for OR case carts); SPS consumable supplies area (supplies for RME reprocessing); non-critical RME storage area (overseen by Distribution Department) that holds cleaned non-critical RME, e.g., intravenous (IV) pumps, sequential compression devices, etc.; sterile preparation room that contains workstations with six Censitrac computers and scanners, and a decontamination area where SPS cleans RME prior to sterile preparation. The SPS area is currently under renovation which will add additional space, and one of the areas will have two additional Censitrac systems added.

III. Specific Allegations of the Whistleblower

1. Sterile Processing staff does not perform decontamination, cleaning, sterilization, packaging, storing, and distribution of medical and surgical device processes in accordance with competencies established by device manufacturers and VA procedures, thus increasing the possibility of contamination.

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[1] Complexity level 1A: complexity levels are determined by patient population (volume and complexity of care), complexity of clinical services offered, and education and research (number of residents, affiliated teaching programs, and research dollars). Complexity level 1 is the most complex and level 3 is the least complex; complexity for level 2 facilities is considered moderate. (Veterans Health Administration Executive Decision Memo (EDM), 2011 Facility Complexity Level Model).

2. Sterile Processing managers emphasize speed over compliance with the competencies.
3. Sterile Processing is grossly understaffed and does not have the manpower to meet the decontamination, cleaning, sterilization, and packaging competencies.
4. Sterile Processing managers falsify official Government documents regarding education and training of medical supply technicians in order to satisfy VA record keeping requirements and pass periodic inspections.

IV. Conduct of Investigation

The VA team conducting the investigation included B6 Deputy Medical Inspector (a surgeon); B6, Registered Nurse (RN), Clinical Program Manager; B6, Clinical Program Manager, all from OMI; B6 Health System Specialist (HSS), VHA National Program Office for Sterile Processing (NPOSP); and B6, HR Specialist. VA reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured the Medical Center's SPS (announced and unannounced) and the OR, and held entrance and exit briefings with Medical Center leadership.

VA initially interviewed the whistleblower via teleconference on August 26, 2015, and face-to-face on August 31, 2015.

The following employees participated in the Entrance Briefing:

- B6, Medical Center Director
- B6, Assistant Director
- B6 Chief of Staff (CoS)
- B6, Administrative Assistant/CoS
- B6 Deputy CoS
- B6, HSS, Program Coordinator for Deputy CoS
- B6, Acting Nurse Executive
- B6, Associate Chief Nurse
- B6, Chief SPS
- B6, Assistant Chief SPS
- B6, RME Coordinator
- B6, Chief Management Support
- B6 Director Quality Management and Performance
- B6 Safety Officer
- B6, Infection Preventionist
- B6, Chief Human Resources
- B6, VISN 18 Quality Management Officer (via teleconference)

We interviewed the following Medical Center Employees:

- B6 [redacted], Acting Nurse Executive
- B6 [redacted], Associate Chief Nurse
- B6 [redacted]., Chief, Surgery
- B6 [redacted] Orthopedic Surgeon
- B6 [redacted] General Surgeon
- B6 [redacted]., Chief, Infectious Disease
- B6 [redacted] Infection Preventionist
- B6 [redacted], Chief SPS
- B6 [redacted], Assistant Chief, SPS
- B6 [redacted], RME Coordinator
- B6 [redacted], Medical Supply Technician, Day Shift Supervisor
- B6 [redacted], Medical Supply Technician, Evening Shift Supervisor
- B6 [redacted], Medical Supply Technician, Day Shift
- B6 [redacted] Medical Supply Technician, Day Shift
- B6 [redacted], Medical Supply Technician, Day Shift
- B6 [redacted], Medical Supply Technician, Evening Shift
- B6 [redacted], Medical Supply Technician, Evening Shift
- B6 [redacted], Medical Supply Technician, Evening Shift
- B6 [redacted], Medical Supply Technician, Night Shift
- B6 [redacted], Medical Supply Technician, Night Shift
- B6 [redacted], EMS Supervisor
- B6 [redacted], Nurse Manager, Gastroenterology
- B6 [redacted] Nurse Manager, Urology
- B6 [redacted] Nurse Manager, OR
- B6 [redacted], Circulating Nurse
- B6 [redacted] Circulating Nurse
- B6 [redacted], OR Technician

The following employees participated in the Exit Briefing:

- B6 [redacted], Medical Center Director
- B6 [redacted], Associate Director
- B6 [redacted], Assistant Director
- B6 [redacted].D., CoS
- B6 [redacted]., Deputy CoS
- B6 [redacted], Acting Nurse Executive
- B6 [redacted], VISN 18 Patient Safety Officer (via teleconference)

V. Findings, Conclusions, and Recommendations

Allegation 1: Sterile Processing staff does not perform decontamination, cleaning, sterilization, packaging, storing, and distribution of medical and surgical device processes in accordance with competencies established by device manufacturers and VA procedures, thus increasing the possibility of contamination.

Background

SPS employees reprocess RME medical devices and instruments for use on multiple patients. RME falls into essentially three different processing categories: clean, high-level disinfect, and sterile. Each share similarities, the focus of the investigation was on high-level disinfection and sterile RME processing.

Processing of RME occurs in three distinct phases: decontamination; preparation, and sterilization. The decontamination phase involves following the manufacturers' instructions for use (IFU) to address soiled items. This phase involves receiving, sorting, soaking, cleaning, and rinsing in a manner that is specific for each piece of equipment. In the preparation phase, medical supply technicians (SPS technicians) inspect the equipment received from decontamination, assemble the equipment into sets, and place the sets into packages. They then label the packaged instrument sets and place them in the sterilizer. The sterilization phase is the physical processing of the cleaned instruments in the appropriate sterilizer/cycle. Sterilization is either a chemical process or a heat, temperature, and pressure process, depending on the requirements of individual instruments. After sterilization, SPS employees store sterilized instruments in a temperature and humidity-controlled sterile storage area.[2] In sterile storage, the SPS technician assembles case carts comprised of individual instruments or sets that are used by staff throughout the Medical Center. After use, the end users return the instruments to decontamination for reprocessing. VHA has directed the use of governing standards for instrument processing from the International Association of Healthcare Central Service Material Management (IAHCSMM), and the Association for the Advancement of Medical Instrumentation (AAMI). Guidance to use IAHCSMM in lieu of VA Directive and Handbook 7176 was issued on May 8, 2012.[3] Each piece of equipment has specific instructions for cleaning, processing, and sterilization in the manufacturers' IFU. VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment in Veterans Health Administration Facilities*, states: "It is VHA policy that systematic and local standard processes are developed in compliance with manufacturer's instruction, infection prevention and control principles, and effectively communicated and deployed to staff wherever procedures using RME are performed." Using these standards and the IFU, the Medical Center develops specific standard

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[2] Central Service Technical Manual, seventh ed. International Association of Healthcare Central Service Materiel Management (IAHCSMM) 2007.

[3] Guidance outlining the use of IAHCSMM in lieu of VA Directive and Handbook 7176 is located at: http://vaww.ceosh.med.va.gov/01IH/Pages/ST_MedicalSterilizers.shtml

operating procedures (SOP) which serve as a guideline when handling this equipment. There must be specific processes and procedures in place for all RME.[4]

SPS technician training includes competencies developed from SOPs incorporated into an evaluation checklist. Under VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements*, the responsibility for training individual staff/technicians falls under the Chief of SPS. This directive states:

> Any and all individuals charged with reprocessing duties are appropriately trained and competent in performing the assigned tasks, and when SOPs are changed all designated staff are retrained and competency is again established. Personnel reprocessing RME must be continually evaluated to ensure that they are demonstrating proficiency in all reprocessing activities and meeting all critical elements in their performance standards relating to RME. Appropriate training must be done whenever new or different equipment is used; new critical elements related to reprocessing must be added to performance standards, as necessary. Temporary personnel must not be permitted to reprocess RME until training has been completed and proficiency has been demonstrated.

This directive also states that the facility director is responsible for "Processes for determining which equipment is to be utilized, involve all the stakeholders, and include the needs and training of the operator, infection control, logistics, SPD, and Biomedical Engineering."[5]

The whistleblower indicated that on inspection, the OMI team would find "one date on all competencies," and that staff are given "a stack of papers to sign just before an inspection."

Findings

VA reviewed the most current competencies of SPS employees. We found that the SPS leadership had all the required competencies and SOPs in place, and the folders comply with VA guidelines. There were 19 binders of competencies and SOPs. During the review of the competency folders, we found that both the trainer and the trainee signed-off SOPs and competencies throughout the year in 2015. The distribution of sign-off dates included: 3 in January 2015; 21 in February 2015; 11 in March 2015; 2 in June 2015; 7 in July 2015; and 15 in August 2015. We found that 100 percent of the current sign-off dates correspond with employee work days on the work schedule.

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[4] VHA Directive 2009-04, Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities, February 9, 2009 http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=1824

[5] VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements, June 26, 2009 http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=2039

SPS underwent two external inspections in fiscal year (FY) 2015: NPOSP on September 23-25, 2014, and The Joint Commission (JC) survey on March 31-April 1, 2015. In February and March 2015, the supervisors signed-off on 32 of the 59 competencies, as part of their annual competency evaluation. This coincidentally preceded the JC inspection. The Medical Center received notification of the VA team investigation on August 20, 2015. There were nine pieces of equipment signed-off on after August 20, 2015, and four signed-off in March 2015. However, these sign-offs also coincided with the release of SOP 15, *Cleaning, High Level Disinfection, and Sterilization of Flexible Endoscopes and Accessories* (dated August 2015), which included a new series of competencies requiring sign-off.

Out of the nine current SPS technicians and two supervisory technicians interviewed, no one reported having seen SOP violations. All of the employees could articulate the importance of their work and the notion that the work they do involves Veterans' lives. None of the interviewees said that the SPS leadership (Chief, Assistant Chief and Supervisors) instructed them to skip steps in SOPs in order to get RME processed more quickly. The evening supervisor stated that leadership is very precise and if an error occurred that could affect patient care, then leadership is "hard" on these errors, and she also stated that leadership provided additional training and assistance after counseling the employee. Only one former SPS technician (the whistleblower) admitted to skipping steps in SOPs. Both the day and evening shift supervisors denied ever witnessing anyone "cut corners" to process equipment despite high volume. The Chief of Surgery described SPS leadership as "almost paranoid" about processing equipment in accordance with SOPs.

The March 2015 JC Inspection revealed some concerns in the decontamination area. In particular, procedures for use and monitoring of chemical solutions (Cidex®, and enzymatic solutions) were not in accordance with the IFUs for expiration dates for the chemicals or the soak times for instruments. During this inspection, we found that specialized equipment areas had only the relevant SOPs for that specific processing area posted to avoid confusion, that all posted SOPs were up-to-date, and that timers were available if required for RME processing to ensure compliance with IFU-directed soak times in the various detergents and solutions. We also found that SPS staff could articulate the SOPs for use and monitoring of chemical solutions, and all staff pointed out the information available for reference.

The Medical Center puts sterile storage equipment in both SPS and in a smaller supply in the operating room core area. Instrument trays were orderly, properly labeled, and easy to access, and we did not observe excess clutter.

As an example of an ongoing quality assurance (QA) program, SPS staff and leadership reported that they had identified issues regarding holes in wrappers in July 2015. They were able to link this problem with a specific vendor tray. This was subsequently addressed with the vendor, resulting in a decrease in wrapper holes as a result of intervention. In addition, these incidents were documented in the Surgical Care Quality Improvement Program's Corrective Action/Prevention Action (CAPA) reports that

showed that there were 23 occurrences in 2014, and 10 from January to August 2015. The CAPA reports also showed that the SPS leadership implemented corrective actions in July 2015 to reduce the incidence, but it is too early to tell if the changes had any effect.

One OR nurse described an event regarding the handling of a new piece of equipment by the SPS staff. A new instrument had been purchased by the OR outside of the normal purchasing process, and therefore SPS staff was not aware that it was in-house. The instrument was on a shelf in the OR supply room in the vendor package, instead of in the SPS sterile storage area, as is the normal procedure. Approximately 3 weeks later, the surgeon asked to use the new instrument (for a next-day surgery), and the OR nurse sent the equipment to SPS for processing. Because this was a new piece of equipment, there were no SOPs or competencies on the new item. Prior to use, the Assistant Chief, SPS, requested the IFU from the OR so that she could write an SOP and provide training to the SPS technicians. In this way, the Assistant Chief, SPS, enforced the standards regarding the importance of SOPs and proper training, despite pressure. A similar finding demonstrating cooperation between the OR and SPS was noted in the NPOSP inspection in September 2014, also indicating SPS leadership's consistency in enforcing SPS standards.

The Chief, Infection Control Committee (an infectious disease physician), indicated that the overall infection rates at the Medical Center are lower than reported in national averages for similar cases.

The Infection Preventionist (an RN) provided an example of the consultation and collaboration between her office and the SPS leadership. In June 2014, on routine surveillance, the Infection Preventionist identified an increase in the infection rate on the patients of a specific provider on one service. The infections were isolated to cases where a specific instrument that was technically difficult to clean was used. The SPS staff had recognized difficulties cleaning this instrument as it could not be fully disassembled, and they communicated their concerns to the infection control committee as a possible infection risk. The surgeon whose infection rates had increased was the only surgeon who used this instrument, and he had used the instrument in all of the cases that resulted in infection. The Medical Center leadership immediately removed the instrument from the system, and this surgeon's infection rate returned to acceptable levels. As a result of the combined efforts (SPS providing concerns over possible contamination, and the routine surveillance by infection control), this issue was resolved.

VA reviewed the Surgical Care Quality Improvement program's CAPA reports for calendar year (CY) 2014 and CY 2015. In 2014, 35 different events were reported (average 2.9 per month), and in 2015 (through August), 33 events were reported (average 2.75 per month). The findings regarding concerns of missing or incorrect instruments in trays, incorrectly labeled trays, moisture in tray, and holes in exterior wrapping, were similar to those reported to the VA team by the SPS staff and leadership. There were six total cases of reported bioburden found in trays in the

2-year period.[6] The Medical Center staff performed 4,690 surgical cases from April 1, 2014, to March 31, 2015, resulting in a rate of 0.06/100 cases for the presence of residual bioburden for the year. The OR staff reported a "low" rate of bioburden present on instruments and identified all cases prior to placement on the sterile field; therefore, none of these instruments were used on patients.

VA reviewed the Medical Center Infection Control Committee's (ICC) documentation on the clean wound infection rates for 2012 through 3rd Quarter FY 2015.[7] The clean wound infection rates from the ICC report showed an increase in FY 2012, followed by 2 years of declining rates in FY 2013 and FY 2014. Multiple parameters affect this rate including patient preparation, complexity, and pre-existing conditions; however, it is a useful bellwether to provide an overall state of safety for patients

The percentage of intermediate and complex cases at the Medical Center was higher than the national average with the number of complex cases twice as high as the national average (4.7 percent for the Medical Center, and 2.3 percent for the national average). The VA Surgical Quality Improvement Program (VASQIP) report produced by the VA National Surgery Office uses combined clean, clean contaminated, contaminated, and dirty or infected rates as opposed to the ICC report discussed above which only included clean wound infections. The Medical Center has a combined rate higher than the national average. The clean surgical site infection rate for the rolling 12 months (April 2014-March 2015) is higher than the national average. The rates have been on a downward trend since the initial increase in 1st Quarter FY 2013 when the Medical Center's overall rates first exceeded the national average.

Another example of the Medical Center's active quality improvement program is demonstrated by their response to an increase in clean surgical infection rates in FY 2012: the Medical Center implemented a policy using Cloraprep (a chlorhexidine/alcohol product), instead of the previous policy of chlorhexidine alone or betadine alone for surgical preparation. As a result, the clean surgical infection rate in FY 2013 declined by nearly half through 4th Quarter of FY 2014. There is a trend in the Medical Center's ICC reports indicating a higher-than-expected complication rate for urology procedures in FY 2015. As a result of these rates, the Medical Center analyzed

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[6] Bioburden is foreign material (e.g. blood, tissue, bone, etc.) that remains on instruments after use.

[7] **Wound Class: Clean Wound**-A clean wound is an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. **Clean-Contaminated Wounds**-Clean-contaminated wounds are operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. **Contaminated Wounds**-Contaminated wounds include open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in the category. **Dirty or Infected Wounds**-Dirty or infected wounds include old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

the data and requested a National Surgical Consultation Visit. This visit occured December 10, 2015.

Conclusions

- VA **does not substantiate** the allegation that SPS staff does not perform decontamination, cleaning, sterilization, packaging, storing, and distribution of medical and surgical device processes in accordance with competencies established by device manufacturers and VA procedures, thus increasing the possibility of contamination.
- VA found written evidence of SPS leadership enforcing SOPs and VHA Directives. This is the most comprehensive SOP and competency training program seen by this VA team.
- The Medical Center staff has an engaged QA program that is responsive to periodic rate changes as evidenced by the downward trend in the VASQIP reported rates over the last 3 years.
- VA identified one example of initial poor communication between the operating room staff and SPS related to procuring a new surgical instrument, which added undue stress to SPS personnel who were trying to meet OR needs.
- The national requirement that the Medical Center SPS leadership develop extremely detailed SOPs and competencies for each individual piece of RME, a duplication of the manufacturers' IFU, is a labor-intensive process, and the management of this process is extremely cumbersome at a busy Level 1 facility.

Recommendations to the Medical Center

1. Review the requirements that mandates writing SOPs on each individual piece of RME, to determine how to make the competency assessment process more efficient.

Recommendation to VHA

1. Review the requirements that mandate writing individual SOPs on similar pieces of RME to determine how the competency assessment process might be made more efficient.
2. As recommended in OSC File Number DI-15-2103, VHA should publish a handbook to address the specific SPS portions of VA Directive and Handbook 7176, *Supply, Processing, and Distribution*, as soon as possible.

Allegation 2: Sterile Processing managers emphasize speed over compliance with the competencies.

The whistleblower alleged that the Chief of SPS established "production quotas" which increased the risk of SOPs being ignored. The whistleblower stated that the SOPs were "very involved."

Background

The processes in SPS are similar to production line environments: instruments pass through a series of different steps to accomplish specific items before moving to the next step in the process. Each step takes a minimum amount of time to complete. The time per step is sometimes influenced by the intricacies of individual instruments, and sometimes procedures involve automated devices with timed mechanical processes. An example of an automated device is steam sterilizers which takes time to reach operating temperatures and pressures. The technician must select the amount of time the cycle will run depending on the IFU and SOP guidance, and the process time is fixed once a cycle has started in these automated devices.

Findings

During interviews with the VA team, two SPS technicians stated that the SOPs were "perpetual" and "convoluted," related to the extensive and detailed nature of the multiple individual SOPs. None of the current staff interviewed stated that leadership emphasized speed over compliance. Eight of the nine SPS technicians stated that they had heard or been told by SPS leadership to slow down and focus on compliance with the SOPs. The RME Coordinator stated that she had witnessed the SPS leadership give this same advice to the SPS staff.

The Assistant Chief of SPS, indicated that there was a priority system when workload exceeds immediate capacity in the unit. The expectation is that priority trays are done first (i.e. those needed for surgery the next day); one-of-a-kind trays done second; and the third priority are items that are "multiples" which covers more general instrument trays when there are several trays available in sterile storage. There is a status board prominently displayed in SPS which indicates which instruments/sets fall into the first two categories. SPS technicians also described this priority system.

Three SPS technicians stated that they understood speed potentially impacts quality and stated that they had to slow down to ensure proper processing of instruments. Two other SPS technicians volunteered that they were counseled by supervisors to slow down to ensure proper processing. Both of these individuals indicated that SPS leadership wanted both speed (increased efficiencies) and compliance. They denied that they had ever been told to skip SOP steps to work faster. These technicians also described leadership's nonverbal mannerisms giving the message to work faster. One staff member who primarily works with processing endoscopes in the Gastroenterology (GI) lab stated that she never got the impression that she had to work faster. This staff member stated that it was easy for her to get her work done.

Several SPS employees reported feeling rushed to meet their mission requirements and further stated that they did not like the way the Assistant Chief of SPS spoke to them. They reported that they felt the SPS leadership preferred the day shift staff over the evening and night shift staff and that leadership was harder on evening and night shift staff members, administering counseling and discipline for violating SPS policy or

procedures. VA did not find evidence of disproportionate discipline for staff on the evening and night shifts.

Conclusions

- VA **does not substantiate** the allegation that SPS managers emphasize speed over compliance with the competencies; but rather emphasized strict compliance and efficiency with SOPs and competencies.
- VA found that there is a priority system in place to help triage workload when it exceeds immediate staffing resources, and that this system is communicated to and understood by the staff.
- Leadership's communication style and the Medical Center's constant workload increased SPS Technician's level of stress.

Recommendation for the Medical Center

2. Provide training/tools on effective communication for SPS staff.
3. Consult with NCOD or an outside consultant to implement team building for SPS staff on all tours of duty.

Allegation 3: Sterile Processing is grossly understaffed and does not have the manpower to meet the decontamination, cleaning, sterilization, and packaging competencies.

Background

In 2009, VHA reorganized the Sterile Processing Distribution (SPD) Department. SPS technicians were organizationally relocated from Medical Logistics to the Nursing Service, which resulted in a change in promotion opportunity. NPOSP in 2012, requested that the VA qualification standard for the SPS technician classification be changed from GS to Title 38 hybrid employee status, to more closely match the highly-technical nature of the work and to allow for more flexibility for pay and advancement. The classification from GS to Title 38 hybrid employee status was finalized in September 2014. The Medical Center leadership including the Chief of SPS is aware of this change in classification and has been working to get vacant positions changed to the Title 38 hybrid, prior to hiring new staff to fill vacancies. Additionally, the Medical Center leadership planned to hire the higher (GS-6) positions internally before looking to fill other positions (GS-5) from outside the SPS Department. The rationale presented by Medical Center leadership was to promote qualified staff from within and to recognize the SPS technician skill level to improve retention of qualified employees.

Findings

The Medical Center suffered several losses in SPS staff due to attrition. This has been an issue for approximately 1 year. There were four vacant SPS Technician positions advertised on USA jobs on August 21, 2015. Also, at the time of our visit, there were

two SPS Technicians on long-term medical leave, one whose leave started in May 2015, and the second one whose leave started in July 2015. The SPS was authorized 20 SPS technicians, including shift supervisors. With four vacant positions and two technicians on long-term medical leave, there were 14 available staff (70 percent). To make up for the shortfall, all supervisors actively work in the department on a daily basis including the Chief of SPS and Assistant Chief of SPS. The direct participation of supervisors in SPS workload brought staffing up to 16/20 (80 percent), but has resulted in supervisors splitting their time between clinical and administrative duties. The Medical Center Director is aware of staffing concerns and indicated that several individuals had applied and were certified by HR as qualified for the four vacant positions. Interviews were to begin on September 4, 2015 (the day after the VA team exit briefing). Existing personnel had their schedules changed in order to meet staffing needs and accommodate workload. The majority of the decontamination/processing staff are on the evening shift. Most of the SPS staff work 11:00 a.m. to 7:30 p.m. or 3:00 p.m. to 11:30 p.m. (seven staff were assigned on these two shifts as of August 2015). Workload is a continuum across shifts, and communication is established by the SPS staff using the priority system and message board, as noted above. Although efforts are underway to fill vacancies, there is no temporizing plan (such as temporary contract staffing) to mitigate deficiencies in available staffing. Although VA notes that temporary contract employees would create an additional burden of competency training and certifications on an already stressed system.

As noted in findings above, there is no evidence that SPS staff is not meeting the decontamination, cleaning, sterile processing, and packaging needs of the Medical Center. There are quality indicators in place, i.e., incident reports, CAPA forms, Surgical Care Line Quality Improvement forms, to monitor compliance with standards. They actively monitor these quality indicators and have a responsive quality and performance improvement program.

Conclusions

This allegation is divided into two parts to provide better clarity.

- VA **substantiates** that sterile processing is understaffed. While we appreciated leadership's attempt to provide promotion opportunities for current employees, they have stretched the available SPS staff to the maximum.
- VA **does not substantiate** that the current manpower is not meeting competencies. Productivity and quality of instruments and trays to date have met the needs of the Medical Center; however this has required SPS leadership to fill vacancies and is unsustainable.

Recommendations for the Medical Center

4. Fill SPS technician vacancies as soon as possible and consider the use of temporary contract staff in SPS while new staff is brought onboard and trained.

5. Continue to monitor the SPS quality indicators (e.g., OR incident reports, CAPA forms, SCL QI forms, etc.) for trends and continue to take appropriate actions in response.

Allegation 4: Sterile Processing managers falsify official government documents regarding education and training of medical supply technicians in order to satisfy VA record keeping requirements and pass periodic inspections.

Background

There are two different types of training conducted in SPS: training using VA's Talent Management System (TMS) which is computer-recorded standardized training and competency which is on-the-job skills training. TMS training requires the learner to have access to the TMS system through a username and password to access a library of training. Some of the training is for specific positions or specialties, and other training is available in the library for the learner if they have a particular interest. The TMS training is self-paced and allows for exit, re-entry, and remediation/retesting providing a flexible adult learning environment. The learner can use both internal (within the training material) and external resources during the training to facilitate learning and achieve a passing score, if required. The computer used by the SPS staff to check emails and complete TMS training is in the hallway area outside the Chief of SPS and Assistant Chief of SPS' office. Training can also be completed via computers outside the VA network (i.e. a home computer with internet connection).

The Medical Center conducts competency training in either a demonstration and performance or an observation and performance format. They structure both initial or new procedures and equipment training to ensure full compliance with SOPs and competency checklists. This is done using demonstration by the trainer followed by performance of the task by the trainee. The competency verification process evaluates staff on SOP compliance and can be completed by either an active demonstration by the trainee or by the trainer observing the employee working. In either evaluation format, the trainee and trainer sign the training documentation which indicates compliance with standards for the task.

The whistleblower specifically alleged that:

a. The Chief of SPS completed annual training requirements in TMS for a specific individual and that periodic (specifically annual) training on competencies happens only when there is an impending inspection by an outside agency.
b. The staff is instructed to "take the competencies home" to get them done, and
c. The Chief of SPS would sign competencies after she observed staff performing the task.

Findings

All members of SPS leadership denied completing training for staff. Three of four SPS leaders stated that they assisted staff with logging into TMS and would assist staff that had challenges working with computers. The SPS leadership also reported helping staff find the correct resources during training, i.e. with locating the appropriate reference material. The whistleblower alleged that there was one SPS technician for whom the Chief of SPS had completed training, but both the Chief and the named technician denied the allegation. This technician did state that the Chief of SPS helped her find resources for difficult portions of the training like microbiology. Of the eight SPS staff interviewed, six denied that SPS leadership completed training for others. One stated that she witnessed the Chief of SPS doing TMS training for three SPS technicians, not including the one, indicated by the whistleblower. Two of the three SPS staff members identified by this second allegation denied that the Chief of SPS did their training. However, the third staff member stated that he had provided the Chief of SPS with his username and password for her to help him complete the training so he could "get off the delinquent list" and get back to work. He reported that this occurred in October 2014. VA reviewed this SPS technician's training record in TMS, which indicated that he had 18 TMS recorded training events in the October 2014. One of these entries was an automatic system update of a training course that appears in multiple employee records at the same time and date. Of the remaining 17 training events, 16 occurred on the SPS staff member's shift, and one training event occurred while the staff member was on sick leave.

VA detailed the review of competency training in connection with Allegation 1. As discussed, VA observed increased sign-offs before the JC inspection in March 2015, but this represents 32 of the total possible 108 competencies listed (annual and biannual combined) in the supplied documents and coincided with annual training. The VA team compared staff meeting minutes which also document training/updates on new or problematic equipment. In April 2014, the Sterrad sterilizers were discussed in staff meeting minutes. Review of the individual competencies for these pieces of equipment revealed sign off dates as follows: 3 in April 2014; 4 in July 2014; 2 in August 2014; 2 in September 2014; 1 in October 2014; and 2 in February 2015. The date variance can be explained by the individual training calendar for each technician and availability of staff on the day of the staff meeting. There was also documentation in the staff meeting minutes of August 5 and 6, 2015, of update training about specific endoscopes (models CYF-5 and TJF Q180V) as a result of feedback by end users and changes in the IFU. When compared to the competency dates in the training documentation, the sign off dates were March and April 2015. The later dates are the actual annual skill certification requirements, and the former date reflects an update in procedures that did not require full recertification.

Conclusions

- VA was **not able to substantiate** the allegation that Sterile Processing managers falsify official Government documents regarding education and training of medical

supply technicians in order to satisfy VA record keeping requirements and pass periodic inspections. If the Chief of SPS did actually complete training for a staff member, both individuals may have violated Federal laws.

- There is extensive evidence of ongoing training and education throughout the year, which is not associated with external inspections.
- There is a verbal report of training being completed by the Chief of SPS for a subordinate which could not be confirmed.

Recommendation for the Medical Center

6. At the direction of the investigation team the Medical Center convened an Administrative Investigation to reconcile the contradictory testimony about a supervisor completing TMS training on behalf of an employee. This investigation is underway; if evidence is found that substantiates the allegation, take appropriate administrative and disciplinary action.

Summary Statement

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, OGC has provided a legal review, VHA HR has examined personnel issues to establish accountability, and OAR has reviewed the report and has or will address potential senior leadership accountability. The Medical Center's potential violation of law, rule, and regulation is being addressed by an Administrative Investigation.

Attachment A

IAHCSMM Central Service Technical Manual, seventh edition, *SPS Guidance*, in lieu of rescinded VA Directive and Handbook 7176, May 8, 2013.

IAHCSMM Central Service Technical Manual, seventh edition. International Association of healthcare Central Service Material Management, 2007.

VHA DIRECTIVE 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009.

VHA DIRECTIVE 2009-031, *Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements*, June 26, 2009.

SPS staffing schedules, January 2013 – August 2015

Staff competency folders for SPS

The Joint Commission Accreditation Report, 2015

National Program Office for Sterile Processing SPS Site Review, 2014

VA National Surgery Office Annual Surgery Reports 2013, 2014

VA National Surgery Office Quarterly Report, 2nd Quarter, 2015

Infection Prevention Annual Reports, 2013, 2014

Infection Prevention Quarterly Report, 3rd Quarter, 2015

OR incident reports involving SPS, 2013-2015

Infection prevention minutes, August 2014

Neurosurgery Review, October 2013- June 2014

SPS competency spreadsheets, 2014, 2015

Training Management System documentation for SPS staff, 2014-2015

SPS staff meeting minutes, 2013-2015

Completed SCL QI data collection CAPA forms, 2014 – 2015

VA Memorandum, "Clarification of Organizational Responsibilities Related to Sterile Processing and Distribution (SPD) and Processing Reusable Medical Equipment (RME)," October 26, 2009.

VA Memorandum, "Official Name Change for National Program Office for Sterile Processing," December 21, 2011.

VA Memorandum, "Occupations Reviewed by the Joint Classification Working Group-Authority to Advertise Positions at the Incumbent Grade," September 24, 2014.

VA Memorandum, "Request for Revision of the Existing Qualifications Standard in VA Handbook 5005/76 for Hybrid Title 38 GS-622 Medical Supply Technician (Sterile Processing Service Technician (SPST)," December 10, 2014.

VA Memorandum, "Conversion of Medical Supply Technician (GS-0622) to Title 38 Hybrid Status," May 14, 2012.

Department of Veterans Affairs

STRATEGIC COMMUNICATION REVIEW

NAME OF ORIGINATOR	VAIQ NO	DATE	DATE DUE
B6 (OMI); (202) 443-5080	7632920		1/21/16

NAME OF EXECUTIVE SECRETARY STAFF	SUBJECT
Nhi Nguyen	VA Report OSC File No. DI-15-5181, Sterile Processing, Tucson Veterans Affairs (VA) Medical Center (the Medical Center), Tucson, Arizona

ROUTING	INITIALS	DATE	COMMENTS
☒ EXEC SEC	BM	1/20/16	
☒ SENIOR ADVISOR			
☒ COSVA		1/20/16	
☐ DEPSECVA			
☐ SECVA			

KEY POINTS

- Report responds to a whistleblower's allegation that employees in Sterile Processing Service (SPS) fail to properly treat reusable medical equipment (RME)
- The Office of the Medical Inspector (OMI) assembled and led a VA team on an unannounced site visit to the Medical Center on August 31 to September 4, 2015.
- VA partially did not substantiate two allegations, partially substantiated the third, and was not able to substantiate the fourth, and made six recommendations to the Medical Center and two to VHA.

CONCURRENCE

B6 (OAR) 12/29/15; B6 (OGC) 12/29/15; B6 (VHA) 1/13/16

EXECUTIVE SUMMARY

Purpose - Discussion - Recommendation

Purpose: To obtain approval of a report to the Office of Special Counsel (OSC) on the allegations of a whistleblower at the Tucson VA Medical Center.

Discussion: This report to OSC contains six recommendations to the Medical Center to develop an operating room protocol to notify SPS when RMEs are acquired directly from outside vendors, to train and develop teamwork in SPS, to fill vacancies and employ contract help as needed, to continue monitoring SPS quality indicators, and to convene an Administrative Investigation to reconcile contradictory allegations and take appropriate action. VA recommends that VHA review requirements mandating writing standard operating procedures on each and every RME item and publish a handbook to address the specific SPS portions of VA Directive and Handbook 7176, *Supply, Processing, and Distribution*, as soon as possible. OMI, the Office of General Counsel, and the Office of Accountability Review worked together on the report prepared at OSC's request and in accordance with requirements of 5 U.S.C. 1213(d)(5).

Recommendation: We recommend COSVA approves the report and submits it to OSC.

2015-D-6836

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SPECIAL HANDLING INSTRUCTIONS	DATE OF INCOMING	DATE VA RECEIVED	DATE OF INTERIM	DATE RECEIVED IN 001B
☐ RUSH ☐ DATE DOCUMENT FOR ☐ NOTARIZE				1/15/16

VA FORM 0907
SEP 2014