



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON
November 15, 2011

41045

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

Re: OSC File No. DI-11-1625

Dear Ms. Lerner:

Enclosed is the Department of Veterans Affairs' (VA) report in response to your request of May 12, 2011, to investigate allegations that VA employees at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi, violated Federal criminal statutes by issuing false information to the public, congressional staff, and Veterans.

The Veterans Health Administration investigated these allegations and determined that no criminal violations or other wrongdoing occurred. As a result, as detailed in the enclosed report, VA is taking no action.

I have reviewed the report and concur with the findings and conclusions. Thank you for the opportunity to respond to this issue.

Sincerely,

Eric K. Shinseki

Enclosure

11-15-11 10:45 AM

OSC Jackson VAMC-DI-11-1625 Report

I. SUMMARY OF INFORMATION WITH RESPECT TO WHICH THE INVESTIGATION WAS INITIATED

An investigation was conducted in response to a May 12, 2011, letter from the Office of Special Counsel (OSC) (OSC File No. DI-11-1625) regarding allegations made by a former employee at the G.V. (Sonny) Montgomery VA Medical Center (VAMC) that VAMC management “violated 18 U.S.C. § 1001 and 18 U.S.C. § 1505 by issuing false information to the public, congressional staff, and Veterans.” The allegations concerned several VAMC communications made in response to an October 21, 2010, OSC news release that stated that the Agency had substantiated “improperly cleaned and poorly sanitized instruments” at the VAMC. The VAMC responded to the OSC news release with its own October 21, 2010, news release; an October 22, 2010, email to VAMC staff; a “Dear Veteran” letter distributed throughout the VAMC; and November 9, 2010, briefings to congressional and VA Central Office staff. The whistleblower alleged that these VAMC communications contained false information.

II. CONDUCT OF THE INVESTIGATION

The Veterans Health Administration (VHA) assigned two executive assistants within Network 16—the Network in which the VAMC is located—to investigate these allegations. On June 23, 2011, the investigatory team submitted its findings to the VA Office of General Counsel, which determined that the investigation was insufficient and requested that VA’s Office of Inspector General (OIG) conduct the investigation. When OIG declined to investigate, OGC requested that VHA assign the investigation to employees with more investigatory experience. On August 10, 2011, VHA’s Deputy Under Secretary for Health for Operations and Management convened an Administrative Investigation Board (AIB) consisting of the Director of the VA Connecticut Healthcare System; the Acting Director, Office of Public & Intergovernmental Affairs, Southeastern Region; and a Human Resources Consultant from VHA’s Human Resources Management Group. The AIB conducted a 2-day site visit at the VAMC on August 30 and 31, 2011, and obtained sworn testimony from eleven witnesses. One former employee testified, but not under oath. An additional former employee—the VAMC Director at the time that the alleged wrongdoing occurred—testified under oath by conference call on September 30, 2011, as she was out of the country when the AIB initially attempted to contact her.

III. SUMMARY OF EVIDENCE

On August 25, 2009, OSC referred a whistleblower complaint (OSC File No. DI-09-3272) to the Secretary. The whistleblower alleged that the staff at the VAMC “...consistently failed to sterilize medical instruments (i.e., reusable medical equipment (RME)) between uses, and that as a result, patients and staff have been exposed to infectious viruses and bacteria on a regular basis for a number of years.” In response to

these allegations, VHA conducted an on-site review on October 22 and 23, 2009. At the end of this on-site review, the review team held an exit briefing with VAMC management. The AIB substantiated through sworn testimony that management's impression during and after the exit briefing was that the review team found evidence of progress with RME reprocessing at the VAMC, leadership was engaged and had committed appropriate resources to reprocessing RME, effective checks and balances were in place and generally successful in assuring that RME were cleaned properly, and, importantly, that no violations of RME processes were found.

The AIB substantiated that a report prepared by the review team was sent to the VAMC on or about December 21, 2009. (Attachment A) In that report, numerous clinical areas were mentioned, the Podiatry Clinic was given more emphasis than other clinical areas, and the time period of 2001-2006 was highlighted more than other specific time periods. The report also included the following statement: "The VHA team finding regarding violation/apparent violation of regulations, directives, or policies is that although there are opportunities to improve the reprocessing of RME, we found no violation/apparent violation of VHA or Medical Center regulations, directives, or policies." (Attachment A at 11) (emphasis added) The AIB substantiated that this site visit report was the first of two versions of the report. The second version was the version submitted to OSC on May 5, 2010, and contained a substantial change in language, as the second version stated that the review team found "occasions when staff violate policy by failing to ensure that RME are properly cleaned and sterilized." (Attachment B at 16) The cover letter submitted to OSC from the Secretary also stated that VAMC employees failed to follow VA policy. However, the AIB substantiated that the existence of the report that was submitted to OSC was not known by VAMC management until June 2011, when the investigatory team that initially investigated these false statement allegations questioned the VAMC Chief of Staff. In essence, it appears that the 2009 review team's initial findings—that no violations occurred—were changed at the VA Central Office level, but that this change was never communicated to the VAMC until OSC notified the Agency of the false statement allegations through the May 12, 2011, letter.

On October 21, 2010, approximately 9 months after the "no violations" report was received by the VAMC, OSC issued a news release that was noticed by the Associated Press ("AP") (Attachment C). An AP journalist contacted the VAMC's Public Affairs Officer to ask if the VAMC had any comment regarding the OSC news release. The AIB noted that in the OSC news release Podiatry is the sole clinical area specifically mentioned—and Podiatry was mentioned four times—while other areas are mentioned in a general way (i.e., "clinics" and "OR").

Later that same day, October 21, 2010, the VAMC issued its news release in response to the OSC news release. (Attachment D) This news release was also the foundation for an e-mail from the VAMC Director to all employees, and a hardcopy letter distributed within the VAMC as a flyer. The VAMC's news release cited only Podiatry as a specific clinical area, focused on the time period of 2001-2006, and specifically cited nail clippers, but no other pieces of equipment used in Podiatry or the many other clinical areas covered in the VHA review team's report. The VAMC's news release also

stated that the review team's report concluded that the VAMC was compliant with all VA regulations, rules, and procedures.

The AIB noted that the OSC news release mentioned several specific "dirty and rust-stained instruments" such as "scalpels, blade handles, tissue and nail nippers, hemostats, and bone cutters." The AIB found, however, that neither VHA reports—neither the initial report sent to the VAMC nor the subsequent report submitted by VA to OSC—mentioned any of these specific instruments, except for Podiatry nail clippers. This discrepancy between the VA report submitted to OSC and the OSC news release led the AIB to surmise that OSC referenced information provided by the whistleblower but not specifically substantiated by the Agency's investigation. This discrepancy was noted by VAMC management, and coupled with the VAMC's belief that the 2009 VHA review time found no violations, led them to believe that the OSC news release was based upon inaccurate information. When the VAMC was asked to respond to the OSC news release, management responded with the only information that it possessed—the initial VHA report that found that the VAMC did not violate policy.

The AIB determined that the VAMC news release contained several statements that VAMC management, at the time, believed to be true. The key statement is the news release's first sentence: "The report regarding the cleaning of Reusable Medical Equipment (RME) in podiatry concluded that the Jackson VA Medical Center was compliant with all VA regulations, rules and procedures." The VA news release's second, third, and fifth paragraphs focus exclusively on the Podiatry clinic, while the fourth paragraph references "all medical equipment." The AIB substantiated that VAMC management focused on Podiatry in its news release because the initial VA report focused on Podiatry more than any other section, and Podiatry was the only section specifically mentioned in the OSC news release. VAMC management also testified that it felt tremendous pressure to respond immediately to the OSC news release, which contributed to the VAMC issuing the news release without first attempting to contact VHA leadership to determine why OSC would announce that VHA found violations at the VAMC, while the report submitted to the VAMC determined that no violations occurred.

The AIB substantiated that all of the subsequent allegedly false communications—the e-mail to VAMC staff, the "Dear Veteran" flyer, and the oral communications with congressional and VA Central Office staff—were based upon the VAMC's response to the OSC news release. It was several months later that VAMC management learned of the existence of the report submitted by VA to OSC that stated that the VAMC had violated Agency policy. Accordingly, the AIB concluded that it found no evidence supporting the whistleblower's allegations that VAMC management made false statements in violation of title 18 U.S.C.

IV. SUSTAINED OR UNSUSTAINED VIOLATIONS

The AIB did not find evidence of criminal violations or other misconduct.

V. ACTION TAKEN

Because there was no evidence of wrongdoing regarding the false statement allegations, the Agency will take no action.

ATTACHMENT A

**U. S. Office of Special Counsel
1730 M. Street, N.W. Suite 300
Washington, DC 20036-4505**

**Report of Investigation to the U.S. Office of Special Counsel
OSC File Number DI-09-3272**

The Secretary of Veterans Affairs asked the Veterans Health Administration (VHA) to review a complaint lodged with the Office of Special Counsel (OSC) by an anonymous employee at the G.V. Sonny Montgomery Veteran Affairs Medical Center, Jackson, Mississippi (hereafter the Medical Center). The complainant raised allegations concerning the health and safety of patients and employees at the Medical Center. Specifically, the complainant alleges:

1. For 5 years, doctors and staff at the Medical Center did not follow Occupational Safety and Health (OSH) Standard Operating Procedures (SOP) 3003 when they failed to sterilize medical instruments. Instruments used on patients for procedures, including minor surgery, are merely wiped with a Sani-Wipe and re-used on the next patient. Doctors and staff regularly exhaust their supplies of clean instruments before they are finished seeing patients, and choose to reuse instruments to see more patients.
2. In the Ear Nose and Throat (ENT) Clinic, nurses have been observed using trays of unsterilized instruments.
3. Staff received sterile instruments that actually had dried blood on them or sterile instruments not individually bagged to preserve sterilization.
4. The lack of sterile instruments has led to patients and staff being regularly exposed to infectious, viruses, and bacteria on a regular basis: Human Immunodeficiency Virus, hepatitis, methicillin-resistant Staphylococcus aureus, bacterial-fungal infections, and warts. Veterans have not been notified of their possible exposure or tested for any infection that may result from such exposure.
5. Although management official are aware of this continuing public health danger, they have taken no action to address the problem.

Facility Profile

The Medical Center is a tertiary care facility classified as a Clinical Referral Level 1 teaching hospital with several affiliations, including, the University of Mississippi School of Medicine. It oversees Community Based Outpatient Clinics (CBOCs) in Columbus, Hattiesburg, Meridian, Greenville, Kosciusko, Natchez, and Meadville, which serve, Mississippi counties of Attala, Carroll, Holmes, Leflore,

Montgomery, Sharkey, Humphreys, Sunflower, Washington, Covington, Forrest, Jefferson Davis, Jones, Lamar, Marion, Perry, Wayne, Adams, and Wilkinson, along with the Arkansas counties of Chicot and Desha. Comprehensive health care is provided through primary care, tertiary care, and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. The Medical Center is a part of Veterans Integrated Service Network (VISN) 16, with facilities in Mississippi, Louisiana, Texas, Arkansas, and Oklahoma. The Medical Center is fully accredited by Joint Commission Accreditation Hospital Organization (the Joint Commission).

Methods for Conducting the Investigation

The VHA team notified the Medical Center Director of the anonymous complaint and of its plans for an October 22-23, 2009, site visit. The Associate Director coordinated the visit and the investigators received full cooperation from the Medical Center staff as they conducted the visit. The investigative team consisted of the Director, Clinical Investigations, Office of the Medical Inspector, the Clinical/Quality Assurance Liaison for the Office of the Deputy Under Secretary for Health for Operations and Management, an Associate Director Nursing/Patient Services Care, and an Infection Prevention and Control Professional, Infectious Diseases Program Office, Supply Processing and Distribution Liaison.

After holding an entrance conference with Medical Center leadership, the team assessed and interviewed physicians, nurses, and technicians in the following areas: Cardiac Catheterization Laboratory, Respiratory/Bronchoscopy, Genitourinary, Gastrointestinal, Operating Room (OR), Medical and Surgical Intensive Care Units, Radiology/Vascular Procedure Suite, Ophthalmology, Orthopedics, Dental, Podiatry, Dermatology, Emergency Room, and Supply Processing and Distribution (SPD). Individual interviews were conducted with the previous Chief, SPD, Acting Chief, SPD, Acting Assistant Chief, SPD, SPD Supervisor, Patient Safety Officer, Chief, Quality Management, Infection Control Manager, MSRA Coordinator, Chief, Infectious Disease, Chief, Surgery, Associate Director, ENT Physician, Chief, Emergency Room, Chief of Staff and Chief, Nurse Executive. During the visit, the team reviewed the following documents:

- National Infectious Disease Program Office Site Visit Report November 2008
- Email from Medical Center staff
- Position Description Quality Manager/SPD
- Medical Equipment Purchases
- Patient medical records
- Infection Control Minutes
- Clinical Executive Board Minutes

At the conclusion of the site visit, the team held an exit conference with Medical Center leadership.

Background

Supply Processing and Distribution (SPD)

The Medical Center's SPD department, opened in 1991 under the direction of Acquisition & Material Management (A&MM), has two sections: supply/distribution and sterilization. Both appeared to have operated well initially. But SPD was staffed by lower pay grade personnel that were transferred from other locations -such as housekeeping, food service, laundry-and had no formal training in SPD. In 2000, the Chief of Surgery, received frequent complaints from surgical staff about incomplete instrument trays in the operating room, inadequate inventory control of medical supplies, and issues with soiled instruments. In January 2001, the Associate Director held meetings with the Chief of A&MM and Chief of SPD to formulate an action plan, which included an invitation to the Chief of SPD at the Veteran Affairs Medical Center, Little Rock, Arkansas, for a consultative visit. This visit resulted in recommendations to improve staffing, the stocking surgical supplies, and the handling of surgical instruments.

Although the recommendations led to some improvement in SPD in 2001, the Surgical Chief continued to receive complaints of inadequate reusable medical equipment (RME), problems with inventory control and soiled instruments. In an effort to address these concerns, the Medical Center leadership put an operating room nurse in charge of SPD, and reorganized the SPD department. These measures appeared to be effective for a while, but in 2006, the complaints resurfaced. Leadership instituted a Healthcare Failure Mode & Effect Analysis (HFMEA), and implemented its recommendations. Later that year, an Office of Inspector General (OIG) Hotline Complaint 2006 03529-HL-0066 alleged lapses in safety and infection control, i.e., a) patient exposure to HIV/AIDS or hepatitis because of unsterile conditions in surgery and nursing, b) instruments not being sterilized prior to use in surgery, c) instruments not sterilized between cases in surgery, d) operating rooms not appropriately cleaned between cases, and f) an attempt by leadership to cover up poor practices.

VISN 16 tasked a team from the Veteran Affairs Medical Center Shreveport, Louisiana to investigate this complaint but the team could not substantiate the allegations; it did, however, make consultative recommendations. On the basis of this team's report, the OIG closed the investigation. Later, Medical Center leadership hired a Perioperative Healthcare Consultant, who was there for a extended period of time, to review the SPD Program, including, staffing, training, competencies, work flow, inventory control, instrument tracking/trays, and

reprocessing of reusable medical equipment. Following this assessment, a post-anesthesia recovery room nurse was put in charge of SPD as acting Chief; an intern in training is assistant Chief, and this is the current leadership in SPD. Neither of these individuals had prior SPD training. In addition, five staff from SPD retired in 2006, which left the department short of staff.

Over the following year, several actions were taken to address the ongoing concerns about SPD. The VISN leadership met with the Chief of Surgery in 2007 to implement formation of an Operating Room Committee that oversaw SPD and tracked SPD-related issues. Under this oversight, three full time equivalents were approved for the decontamination area, a survey of end users was conducted, and surgical clinicians were included in the purchases of supplies and equipment. Since 2008, the Medical Center has also purchased more instruments with the RME funding from the VISN/VA Central Office. The operating room just recently reached the point where they had enough back up instruments, including for urology and that flash sterilization was dramatically decreased. In addition, over \$100,000 had been spent on Podiatry equipment and instruments.

The Infectious Disease Program Office (IDPO) reviewed SPD in November 2008, and with the exception of those recommendations that require space consideration, all of the recommendations have been implemented.

Over the last year, Medical Center leadership has acted to improve SPD by recruiting a Chief and Assistant Chief, six SPD staff positions, establishing a quality manager position to oversee SPD, and developing policies for critical, semi-critical, and non-critical reusable medical equipment. Leadership also developed a RME Quality Oversight Committee within SPD, review instrument incidences in the OR Committee, and instituted RME Leadership rounds.

When oversight for the components of Supply Processing and Distribution (SPD) that pertained to processing of reusable medical equipment and storage of sterile supplies was moved from Acquisition and Materiel Management under VHA to the Infectious Diseases Program under Patient Care Services (PCS) in VHA, SPD materials were moved from the Acquisition and Materiel Management website and temporarily housed on the website of VHA's Office of Occupational Safety and Health (OSH). At that time PCS was not able to accommodate the need for an SPD website, Acquisition and Materiel Management strongly requested that the SPD information be removed from their website, and OSH permitted the temporary housing of the SPD material to allow for continued access to such material by VHA Medical Centers. When SPD was under Acquisition and Materiel Management, a SPD Advisory Group with members from the Medical Centers was established to generate SPD Standard Operating Procedures (SOPs) to be used as a guide for facilities to develop their own SOPs on a variety of topics. Prior to the listing of these SOPs on the website, there is a note that states: "These SOPs are developed as a guide for the starting point of your local SOPs they must be customized to detail the procedure locally. Local procedures must be signed

and approved at facility. Also at no time will a SOP be written or followed to violate policy." Therefore, the SOP numbered 3003 and titled Instrument Care and Handling is only a guide and not a requirement. The guide can be used by facilities as a starting point and customized as applicable at the local level. The VHA has some national policies that pertain to processing of RME, as well as local policies that are approved by leadership and addresses principles as outlined in SOP 3003. The Medical Center has its policies and SOPs that are facility/equipment specific.

Site Visit Findings

Cardiac Catheterization Laboratory (Cath Lab)

The Cath Lab uses sterile instruments on a daily basis. An examination of instruments from the cath lab's storage area, revealed no outdated or dirty instruments. The technicians, nurses, physician, and resident interviewed had no concerns about the instruments they receive from SPD.

Ear Nose Throat (ENT)

ENT uses and reprocesses their own scopes; however, they rely on SPD for sterile instruments, reporting any shortcomings to the Chief of Surgery and the Patient Safety Manager. In February of this year, ENT reported a lack of properly sterilized and peel packed instruments, a lack of properly sterilized instruments for an entire week, requiring them use disposable instruments and to scramble to get needed instruments from other sources. They estimated that 10 – 12 incidents over the last year.

On August 13, 2009, in operating room Suite 2, a rigid metal lumen suction tube was found to have debris in it, causing contamination of the sterile field. The tube was removed and the new sterile field was established with new equipment. A second tray was readily available, so there was no delay in surgery. In addition, the instrument tray with the dirty tube was mislabeled "OR. Ridig Esophagoscopy Ridig Scope;" it should have read "Adult Esophagoscopy Set." ENT has also received sterile OR instrument trays with the wrong expiration dates as well as missing instruments.

The nurses and physician in ENT deny using trays of unsterile instruments. Due to their recent experience they are vigilant about examining instruments prior to use. No one interviewed could verify that they observed nurses in ENT using unsterilized instruments. It should be noted that ENT also uses equipment that comes in touch with the skin that does not require sterilization.

Because SPD staff are required to sign the instrument trays they prepare, the individual who prepared the sterile instrument trays for OR Suite 2 has been

identified as Bessie Spriggins and nursing leadership is proposing disciplinary action in the form of a 14 day suspension.

Respiratory

The respiratory department does not use instruments requiring sterilization by SPD.

Genitourinary (GU)

GU has one cystoscope which is reprocessed within their department while biopsies are being done. The staff was proud that the scope had not broken down: they had no contingency plans if it did break down. GU has purchased 10 additional cystoscopes, which arrived during this site visit. They do not use sterile instruments from SPD.

Gastrointestinal (GI)

The gastrointestinal section does not use instruments requiring sterilization by SPD.

Operating Room-Post Anesthesia Care Unit (OR-PACU)

The OR has issues with dirty instruments about once a month. The nurses there are observant enough to notice such defects before operations are performed, submitting patient incident reports to nursing for each instance. SPD is also contacted directly to discuss this issue and the OR Committee addresses all incidents of dirty instruments. The OR sometimes receives sterile instrument in packs with no expiration date, the incorrect expiration date, or broken wrappers. Incomplete instrument sets have also been an issued but this has improved. The nurse manager indicated that staff normally double glove, so the susceptibility to infections is minimal. Flash sterilization is rarely required or used. The PACU uses disposable instruments/equipment. There was also incidents where a glidescope blade and a camera were melted during reprocessing

Medical and Surgical Intensive Care Units

The intensive care units receive and use instruments sterilized by SPD. The staff interviewed, including a physician, residents, and nurses, indicated that they had no issues with instruments processed by SPD.

Radiology/Vascular Procedure Suite

Radiology uses relatively few instruments from SPD, but will need to develop a standard operating procedure for pre-cleaning the ones they use. The Ultrasound Vaginal Probe is reprocessed in the examination room after patients have been seen. If they had more room, separating the functions of examination and pre-cleaning would be ideal, but overall there were no complaints with general sterilization. The room lacks a timer and a sterilization logbook for start and stop times. They are getting both.

Ophthalmology

This department has four full-time ophthalmologists, three residents, and no optometrists.

On occasions ophthalmology has received damaged equipment from SPD, and they cannot see the damage except under magnification. They would prefer to have one SPD technician handle their instruments. All tonometers are disposable. They do reprocessing of contact lenses in their department, tips for A and B scans, probes and diagnostic lenses. Gonio lenses are kept in wooden boxes that cannot be sterilized. They have portable timers that attach to their belts and all have good competencies. The physicians are signed off by SPD staff that they are competent to reprocess their equipment.

Radiation Therapy

Radiation therapy uses a Zisper clamp which is pre-cleaned and sent to SPD: the staff had no issues with the sterilization of the clamp by SPD.

Dental

Dental uses many metal instruments sterilized by SPD. Staff there was very complimentary of the service and sterilization of their instruments. The dentist, the dental assistant, and the dental assistant supervisor all indicated that they would allow the use of instruments processed by SPD on themselves or their family.

Orthopedics

Orthopedic clinic does not use instruments from SPD except for wire cutters which do not come into contact with patients. Orthopedics uses sterile instruments in the OR and does have concerns about the processing of drill bits.

Podiatry

Two contract podiatrists have worked for the Medical Center one day a week: one from January 1993–June 2009 and the other February 1998–June 2009. The Medical Center hired a full time podiatrist in 2006 and a second one sometime later. In 2006, the Chief, Surgery received e-mails from the full-time podiatrist expressing concerns that instruments were not being sterilized, and were being wiped off between patients by the contract podiatrists. An investigation by the Chief of Surgery discovered that instrument trays for podiatry were sterilized, but contained an insufficient number of nail nippers, and these were being wiped off between patients in the clinics. This practice was immediately halted and additional instruments purchased. Later that year, the same podiatrist complained that dirty, rust-stained instruments were being sent to the clinic. The Infection Control Nurse cultured the instruments; they were negative for organism growth. The company representative determined that the stains were a build up of calcium. SPD now closely monitors podiatry instruments after sterilization.

Interviews with the podiatrists revealed that at one point things had improved, but problems with blood, and rust-stained instruments has recurred. The investigative team removed five instruments from the podiatry cabinet and found two with what appeared to be dirt/particles on them; all five of the instruments were stained.

The Medical Center has determined that the type and quality of the instruments purchased for podiatry may also contribute to this recurring problem. As instruments purchased for surgery are a higher grade of stainless steel than those in podiatry. In addition, somehow disposable instruments are sent to SPD and get reprocessed and are visibly discolored. Another contributing factor is possibly the well water supply. Recently the Medical Center built a water tower to reduce the mineral buildup on the instruments.

The team contacted the Medical Center following the site visit with some follow up questions: With regard to how long did the contract podiatrists wipe instruments between patients, the initial response was the entire time that they practiced at the Medical Center. On October 27, 2009, the team received the following response after the Medical Center contacted the contract podiatrists in their private practice: "is that prior to 2006, podiatry nippers that had blood products on them were sent to SPD for sterilization. Those nippers that had no signs of blood products were wiped off and placed in a container of high level disinfectant (Cidex) for 20 minutes to kill organisms." This is inconsistent with what we were told during the site visit and as described in the OSC complaint. The team did not interview the contract podiatrists because they no longer work at the Medical Center.

Dermatology

Dermatology uses disposable instruments 99 percent of the time; on rare occasions they may require sterile instruments from SPD. The physicians and nurse practitioner in the clinic stated that on these occasions, instruments have been sterilized appropriately.

Emergency Room (ER)

The team found the ER busy and left to avoid disrupting patient care. An interview was conducted with the Chief of ER, who indicated that neither he nor the other physicians in the ER have found issues with sterile instruments. They are always appropriately sterilized.

SPD

The physical constraints of the preparation, sterilization, and decontamination does not lend to an efficient work flow. The staff in decontamination demonstrated their technique for handling of instruments and articulated the proper cleaning solution that was being used. Decontamination is staffed by three people. During the demonstration by the two SPD technicians, brushing and scrubbing of instruments occurred above the water level, when it should be below water. A contributing factor could be that the sink is extremely low and required constant bending over to accomplish this task. There is no cross training of SPD staff between decontamination and preparation. Each preparation station is equipped with magnified lights that are used by the staff to examine surgical instruments for bioburden/debris. They also indicated that they examine all instrument trays and peel packs after they are removed from the sterilizer, prior to being stored or sent to various departments. Any compromises to the packaging or bioburden/debris seen in the peel packs would require reprocessing and re-sterilizing the item(s).

Summary

The issues with SPD and the reprocessing of RME has been a long-standing issue at the Medical Center. Complaints have been filed with Medical Center leadership, the OIG, and the Office of Special Counsel. These concerns include the inadequate reprocessing of instruments and the exposure of patient and staff to blood-borne pathogens. Several actions have been taken, including review, investigations, consultations, purchase of additional instruments, etc.; however these issues continue to surface. It is the opinion of this investigative team that more focus should be placed on the SPD department and its staff. The SPD needs an experienced Chief, Assistant Chief, Supervisor and lead technician

who understand the operations and requirements of SPD; all staff in the SPD should be fully trained and in-services on RME and other SPD issues be provided to this staff on a regular basis, preferably monthly basis. The physical constraint and lack of cross trained staff would make it extremely difficult to move all of RME to SPD to be reprocessed properly.

Conclusions Based on the Following Allegations

1. For five years doctors and staff at the Medical Center did not follow OSH SOP 3003 when they failed to sterilize medical instruments. Instruments are used on patients for procedures including minor surgery and then merely wiped with a Sani-Wipe and re-used on the next patient. Staff received clean instruments that actually had dried blood on them and/or sterile instruments that were not individually bagged to preserve sterilization. Staff regularly exhausts their supplies of clean instruments before they are finished seeing patient, and choose to reuse instrument to see more patients.

Although the Medical Center does follow guiding principles outlined in OSH SOP 3003 and have taken several steps to improve the SPD's reprocessing of RME, there are still incidents of dirty, rust-stained instruments being sent to the clinics and operating room. The team substantiated that podiatrists in the podiatry clinic prior to 2006, did exhaust their supplies of clean instruments before they finished seeing patients and reused instrument to see another patients. This was corrected by the purchase of more instruments and sterilizing instruments after use.

2. In the Ear, Nose, and Throat Clinic (ENT Clinic) nurses have been observed using trays of unsterilized instruments.

The team did not substantiate that the nurses in the ENT clinic have used trays of unsterilized instruments.

3. Staff received sterile instruments that actually have dried blood on them or sterile instruments are not individually bagged to preserve sterilization.

The team substantiated that staff sometimes receives instruments that have been sterilized that have dried blood or other debris on them or that have problems with sterile packaging, with missing instruments, and are mislabeled.

4. The lack of sterile instruments has led to patients and staff being exposed to infectious viruses and bacteria on a regular basis. As a result, thousands of veterans (many of whom have compromised immune systems) have potentially been exposed to a wide variety of infectious viruses and bacteria without their knowledge including: Human Immunodeficiency virus or HIV, hepatitis, methicillin-resistant Staphylococcus aureus (MRSA), bacterial-fungal, infections, and warts. Veterans have not been notified of their possible exposure or tested for any infection that may be a result of such exposure.

There is a possibility that, in the podiatry clinic, patients may have been exposed to blood borne pathogens with the reuse of RME. None of the employees interviewed expressed concerns about being personally exposed to human immunodeficiency virus, hepatitis, methicillin-resistant Staphylococcus aureus, bacterial-fungal infections or warts.

5. Management official are aware of this continuing public health danger but have taken no action to address the problem.

Over the last several years, management has been acutely aware of the issue with SPD and reusable medical equipment and has taken many actions to resolve them; however some problems continue to exist.

Violation/apparent violation of regulations, directives or policies

The VHA team finding regarding violation/apparent violation of regulations, directives, or policies is that although there are opportunities to improve the reprocessing of RME, we found no violation/apparent violation of VHA or Medical Center regulations, directives, or policies.

Recommendations

1. The Medical Center must continue to examine the issues with RME in podiatry to determine why this section continues to have issues with their sterile instruments, i.e. quality of instruments purchased, elimination of reprocessing disposable instruments, appropriate use of chemicals in decontamination, appropriate use of the sterilizers, etc.
2. The Medical Center must hire, as planned, an experienced Chief and Assistant Chief of SPD and the six FTE that are being recruited as soon as possible.

3. The Medical Center should take immediate actions to assess the learning needs and provide training to staff in SPD to eliminate/minimize the errors that are occurring with RME reprocessing. Level 2 certification of staff should be encouraged and regular in-services to assist staff in obtaining/maintaining certification should be instituted immediately.
4. Ophthalmology should store their Gonio lenses in a container that can be cleaned effectively.
5. The Medical Center should consider cross-training and rotating staff between decontamination and sterile preparation areas to maximize support to SPD. Also ensure that training is provided by a competent instructor, that there is a training record for each SPD employee, and that documents all training, certificate and /or certification.
6. VHA should determine whether or not there needs to be an assessment of the podiatry patients seen by the contract providers, prior to the change in practice that occurred in 2006, the purchase of adequate numbers of instruments that allowed for appropriate sterilization after each individual patient use, for exposure to blood borne pathogens.
7. Management should continue to its efforts to improve SPD, through hiring as timely as possible and through close oversight.
8. The Team recommends that until the appropriated leadership is in place and the needed training completed, the facility not move any more RME processing into SPD.

Actions Taken/Planned

Actions Taken:

- RME Leadership rounds
- OR Committee that review instrument incidences
- RME Quality Oversight Committee
- Conduct an evaluation of the podiatry instruments

ATTACHMENT B



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

May 5, 2010

Mr. William E. Reukauf
Acting Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 218
Washington, DC 20036

Re: OSC File No. DI-09-3272

Dear Mr. Reukauf:

Enclosed is the Department of Veterans Affairs' (VA) report in response to your request of August 25, 2009, to investigate allegations of failure to follow policy that outlines proper procedure for cleaning and sterilization of reusable medical instruments. The anonymous complaint also alleged that management officials at the Veterans Affairs G.V. Sonny Montgomery Medical Center, Jackson, Mississippi were aware of the public health danger and had not initiated actions to address the practice.

VA conducted an on-site investigation of these allegations. The investigation substantiated that employees violated VA policy by failing to ensure reusable medical instruments are properly cleaned and sterilized. In response, VHA conducted a Pre Clinical Risk Assessment Advisory Board and determined the risk to patients was negligible and that no disclosures were required. In addition, the investigative team found that the leadership at the medical center had taken several actions to improve the cleaning and sterilization of reusable medical instruments prior to the site visit.

The report contains eight recommendations aimed at assisting the VA Medical Center in Jackson to further improve reprocessing of reusable medical equipment. Since the site visit, an action plan has been developed and is being followed by Veterans Health Administration (VHA) leadership. The status of the action plan items is described in the recommendation section of the report.

I have reviewed the report and action plan and concur with the findings, conclusions and corrective actions. The Under Secretary for Health and I have asked the National Center for Organizational Development to conduct a site visit and review of the VA Medical Center in Jackson, which will occur within the next month.

Thank you for the opportunity to respond to these issues.

Sincerely,

Eric K. Shinseki

Enclosure

Executive Summary

The Secretary of Veterans Affairs asked the Veterans Health Administration (VHA) to review a complaint lodged with the Office of Special Counsel (OSC) by an anonymous employee at the G.V. Sonny Montgomery Veteran Affairs Medical Center, Jackson, Mississippi (hereafter the Medical Center). The complainant raised allegations concerning the health and safety of patients and employees at the Medical Center. Specifically, the complainant alleges:

1. For 5 years, doctors and staff at the Medical Center did not follow Occupational Safety and Health (OSH) Standard Operating Procedures (SOP) 3003 when they failed to sterilize medical instruments. Instruments used on patients for procedures, including minor surgery, are merely wiped with a Sani-Wipe and re-used on the next patient. Doctors and staff regularly exhaust their supplies of clean instruments before they are finished seeing patients, and choose to reuse instruments to see more patients.
2. In the Ear Nose and Throat (ENT) Clinic, nurses have been observed using trays of unsterilized instruments.
3. Staff received sterile instruments that actually had dried blood on them or sterile instruments not individually bagged to preserve sterilization.
4. The lack of sterile instruments has led to patients and staff being exposed to infectious viruses, and bacteria on a regular basis: Human Immunodeficiency Virus, hepatitis, methicillin-resistant staphylococcus aureus, bacterial-fungal infections, and warts. Veterans have not been notified of their possible exposure or tested for any infection that may result from such exposure.
5. Although management officials are aware of this continuing public health danger, they have taken no action to address the problem.

Conclusions Based on the Following Allegations

1. **For five years doctors and staff at the Medical Center did not follow Occupational Safety and Health (OSH) Standard Operating Procedure (SOP) 3003 when they failed to sterilize medical instruments. Instruments are used on patients for procedures including minor surgery and then merely wiped with a Sani-Wipe and re-used on the next patient. Staff received clean instruments that actually had dried blood on them and/or sterile instruments that were not individually bagged to preserve sterilization. Staff regularly exhausts their supplies of clean instruments before they are finished seeing patient, and choose to reuse instrument to see more patients.**

Although the Medical Center does follow guiding principles outlined in OSH SOP 3003 and have taken several steps to improve the Supply Processing Distribution (SPD)

reprocessing of Reusable Medical Equipment (RME), there are still incidents of dirty, rust-stained instruments being sent to the clinics and operating room. However, thanks to the keen observation of staff in these areas, problematic instruments are identified, removed, and replaced prior to procedures or surgery. The team substantiated that podiatrists in the podiatry clinic prior to 2006, did exhaust their supplies of clean instruments before they finished seeing patients and reused instrument to see other patients. This was corrected by the purchase of more instruments and sterilizing instruments after use. VHA conducted a Pre-Clinical Risk Assessment Advisory Board to determine whether this practice posed a risk to patients treated prior to 2006 and deemed the risk to patients as negligible.

2. In the Ear, Nose, and Throat Clinic (ENT Clinic) nurses have been observed using trays of unsterilized instruments.

The team did not substantiate that the nurses in the ENT clinic have used trays of unsterilized instruments.

3. Staff received sterile instruments that actually have dried blood on them or sterile instruments are not individually bagged to preserve sterilization.

The team substantiated that staff sometimes receives instruments that have been sterilized that have dried blood or other debris on them or that have problems with sterile packaging, with missing instruments, and are mislabeled. Although the issue remains, the facility is aware of it and is addressing it through the OR and Reusable Medical Equipment (RME) Quality Oversight Committees and as stated above, these instruments are identified, removed, and replaced prior to procedures or surgery.

4. The lack of sterile instruments has led to patients and staff being exposed to infectious viruses and bacteria on a regular basis. As a result, thousands of veterans (many of whom have compromised immune systems) have potentially been exposed to a wide variety of infectious viruses and bacteria without their knowledge including: Human Immunodeficiency virus or HIV, hepatitis, methicillin-resistant Staphylococcus aureus (MRSA), bacterial-fungal, infections, and warts. Veterans have not been notified of their possible exposure or tested for any infection that may be a result of such exposure.

There is a possibility that due to the practice of contract podiatrists, who have not worked at the Medical Center since 2006, patients may have been exposed to blood borne pathogens with the reuse of RME. However the Pre-Clinical Risk Assessment Advisory Board deemed the risk to patients negligible. None of the employees interviewed expressed concerns about being personally exposed to human immunodeficiency virus, hepatitis, methicillin-resistant staphylococcus aureus, bacterial-fungal infections or warts.

5. Management officials are aware of this continuing public health danger but have taken no action to address the problem.

Over the last several years, management has been acutely aware of the issue with SPD and reusable medical equipment and has taken many actions to resolve it.

Violation/apparent violation of regulations, directives or policies

The VHA team finding regarding violation/apparent violation of regulations, directives, or VAVHA policies is that there are occasions when staff violate policy by failing to ensure that RME are properly cleaned and sterilized.

VHA concurs with findings and will follow up with the Medical Center to ensure full compliance.

Actions Taken/Planned

1. The Medical Center will continue to examine the issues with RME in podiatry to determine why this section continues to have issues with their sterile instruments, i.e. quality of instruments purchased, elimination of reprocessing disposable instruments, appropriate use of chemicals in decontamination, appropriate use of the sterilizers, etc.

Status

Evaluation of podiatry instruments is ongoing. A different type of instrument is being purchased. The chemicals used in the washer are being evaluated. A podiatrist has been added to the leadership rounds and Oversight Committee. The Medical Center has hired a quality manager for RME.

2. The Medical Center will hire, as planned, an experienced Chief and Assistant Chief of SPD and six FTE that are being recruited as soon as possible.

Status:

Recruitment is underway for a Chief, SPD.
An Assistant Chief, SPD has been hired.
Recruiting/hiring six FTE.

3. The Medical Center will take immediate actions to assess the learning needs of and provide training to staff in SPD to eliminate/minimize the errors that are occurring with RME reprocessing. Level 2 certification of staff should be encouraged and regular in-services to assist staff in obtaining/maintaining certification should be instituted immediately.

Status

Several training courses have been conducted for the staff in SPD.

4. Ophthalmology will store their Gonio lenses in a container that can be cleaned effectively.

Status

The container has been ordered and is in use.

5. The Medical Center will cross-train and rotate staff between decontamination and sterile preparation areas to maximize support to SPD. The Medical Center will also ensure that training is provided by a competent instructor, that there is a training record for each SPD employee that documents all training, certificate and/or certification.

Status

Cross-training has been completed and staff is rotated between decontamination and sterile preparation.

6. A VHA Clinical Risk Assessment Advisory Board (CRAAB) will be convened to assess the risk to podiatry patients seen by the contract providers prior to the change in practice that occurred in 2006, i.e., the purchase of adequate numbers of instruments that allowed for appropriate sterilization after each individual patient use, for exposure to blood borne pathogens. If patients are found to have exposure to blood borne pathogens, disclosures will be made in accordance with VHA Directive 2008-002, Disclosure of Adverse Events to Patients, and the appropriate treatment provided.

Status:

A Pre-CRAAB was convened and determined that the risk to patients was negligible.

7. Management will continue its efforts to improve SPD, through hiring as timely as possible and through close oversight of compliance of the following:
 - a. VHA Directive 2009-004, Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities, February 9, 2009.
 - b. VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements, June 26, 2009.
 - c. VA Handbook 7176, Supply Processing and Distribution, August 16, 2002.

Status

Management has continued oversight through leadership rounds, the RME Oversight Committee, and the OR Committee.

8. Until the appropriate SPD leadership is in place and the needed SPD training is completed, the Medical Center will not realign any further RME processing to SPD from areas where reprocessing activities are currently appropriately managed outside of the central SPD department.

Status

No additional RME reprocessing has moved to SPD.

**U. S. Office of Special Counsel
1730 M. Street, N.W. Suite 300
Washington, DC 20036-4505**

**Report of Investigation to the U.S. Office of Special Counsel
OSC File Number DI-09-3272**

The Secretary of Veterans Affairs asked the Veterans Health Administration (VHA) to review a complaint lodged with the Office of Special Counsel (OSC) by an anonymous employee at the G.V. Sonny Montgomery Veteran Affairs Medical Center, Jackson, Mississippi (hereafter the Medical Center). The complainant raised allegations concerning the health and safety of patients and employees at the Medical Center. Specifically, the complainant alleges:

1. For 5 years, doctors and staff at the Medical Center did not follow Occupational Safety and Health (OSH) Standard Operating Procedures (SOP) 3003 when they failed to sterilize medical instruments. Instruments used on patients for procedures, including minor surgery, are merely wiped with a Sanl-Wipe and re-used on the next patient. Doctors and staff regularly exhaust their supplies of clean instruments before they are finished seeing patients, and choose to reuse instruments to see more patients.
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3. Staff received sterile instruments that actually had dried blood on them or sterile instruments not individually bagged to preserve sterilization.
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5. Although management officials are aware of this continuing public health danger, they have taken no action to address the problem.

Facility Profile

The Medical Center is a tertiary care facility classified as a Clinical Referral Level 1 teaching hospital with several affiliations including the University of Mississippi School of Medicine. It oversees community-based outpatient clinics (CBOCs) in Columbus, Hattiesburg, Meridian, Greenville, Kosciusko, Natchez, and Meadville, which serve Mississippi counties of Attala, Carroll, Holmes, Leflore, Montgomery, Sharkey,

Humphreys, Sunflower, Washington, Covington, Forrest, Jefferson Davis, Jones, Lamar, Marion, Perry, Wayne, Adams, and Wilkinson, along with the Arkansas counties of Chicot and Desha. Comprehensive health care is provided through primary care, tertiary care, and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, and extended care. The Medical Center is a part of Veterans Integrated Service Network (VISN) 16, with facilities in Mississippi, Louisiana, Texas, Arkansas, and Oklahoma. The Medical Center is fully accredited by Joint Commission Accreditation Hospital Organization (the Joint Commission).

Methods for Conducting the Investigation

The VHA team notified the Medical Center Director of the anonymous complaint and of its plans for an October 22-23, 2009, site visit. The Associate Director coordinated the visit and the investigators received full cooperation from the Medical Center staff as they conducted the visit. The investigative team consisted of the Director, Clinical Investigations, Office of the Medical Inspector, the Clinical/Quality Assurance Liaison for the Office of the Deputy Under Secretary for Health for Operations and Management, Associate Director Nursing/Patient Services Care, Infection Prevention and Control Professional, Infectious Diseases Program Office, and the Supply Processing and Distribution (SPD) Liaison.

After holding an entrance conference with Medical Center leadership, the team assessed and interviewed physicians, nurses, and technicians in the following areas: Cardiac Catheterization Laboratory, Respiratory/Bronchoscopy, Genitourinary, Gastrointestinal, Operating Room (OR), Medical and Surgical Intensive Care Units, Radiology/Vascular Procedure Suite, Ophthalmology, Orthopedics, Dental, Podiatry, Dermatology, Emergency Room, and SPD. Individual interviews were conducted with the previous Chief, SPD, Acting Chief, SPD, Acting Assistant Chief, SPD, SPD Supervisor, Patient Safety Officer, Chief, Quality Management, Infection Control Manager, MSRA Coordinator, Chief, Infectious Disease, Chief, Surgery, Associate Director, ENT Physician, Chief, Emergency Room, Chief of Staff and Chief, Nurse Executive. During the visit, the team reviewed the following documents:

- National Infectious Disease Program Office Site Visit Report November 2008
- Email from Medical Center staff
- Position Description for Quality Manager/SPD
- Medical Equipment Purchases
- Patient medical records
- Infection Control Minutes
- Clinical Executive Board Minutes

At the conclusion of the site visit, the team held an exit conference with Medical Center leadership.

Background

Supply Processing and Distribution (SPD)

The Medical Center's SPD department, opened in 1991 under the direction of Acquisition & Material Management (A&MM), has two sections: supply/distribution and sterilization. Both appeared to have operated well initially. But SPD was staffed by lower pay-grade personnel that were transferred from other locations, such as housekeeping, food service, laundry, and who had no formal training in SPD. In 2000, the Chief of Surgery received frequent complaints from surgical staff about incomplete instrument trays in the operating room, inadequate inventory control of medical supplies, and issues with soiled instruments. In January 2001, the Associate Director held meetings with the Chief of A&MM and Chief of SPD to formulate an action plan, which included an invitation to the Chief of SPD at the Veteran Affairs Medical Center, Little Rock, Arkansas, for a consultative visit. This visit resulted in recommendations to improve staffing, the stocking of surgical supplies, and the handling of surgical instruments.

Although the recommendations led to some improvement in SPD in 2001, the Surgical Chief continued to receive complaints of inadequate reusable medical equipment (RME), problems with inventory control and soiled instruments. In an effort to address these concerns, Medical Center leadership put an operating room nurse in charge of SPD, and reorganized the SPD department. These measures appeared to be effective for a while, but in 2006, the complaints resurfaced. Leadership instituted a Healthcare Failure Mode & Effect Analysis (HFMEA), and implemented its recommendations. Later that year, an Office of Inspector General (OIG) Hotline Complaint (2006 03529-HL-0066) alleged lapses in safety and infection control, i.e., a) patient exposure to HIV/AIDS or hepatitis because of unsterile conditions in surgery and nursing, b) instruments not being sterilized prior to use in surgery, c) instruments not sterilized between cases in surgery, d) operating rooms not appropriately cleaned between cases, and f) an attempt by leadership to cover up poor practices.

VISN 16 tasked a team from the Veteran Affairs Medical Center, Shreveport, Louisiana to investigate this complaint but the team could not substantiate the allegations. The team did, however, make consultative recommendations. On the basis of this team's report, the OIG closed the investigation. Later, Medical Center leadership hired a Perioperative Healthcare Consultant, who was there for an extended period of time, to review the SPD Program, including, staffing, training, competencies, work flow, inventory control, instrument tracking/trays, and reprocessing of RME. Following this assessment, a post-anesthesia recovery room nurse was put in charge of SPD as acting Chief; an intern in training is assistant Chief. This is the current leadership in SPD. Neither of these individuals had prior SPD training. In addition, five staff from SPD retired in 2006, which left the department short of staff.

Over the following year, several actions were taken to address the ongoing concerns about SPD. The VISN leadership met with the Chief of Surgery in 2007 to implement formation of an Operating Room Committee that oversaw SPD and tracked SPD-related issues. Under this oversight, three full time equivalents were approved for the decontamination area, a survey of end users was conducted, and surgical clinicians were included in the purchases of supplies and equipment. Since 2008, the Medical Center has also purchased more instruments with the RME funding from the VISN/VHA Central Office. The operating room recently purchased additional instruments to meet the demand of the schedule, including instruments for urology, and has demonstrated a reduction in the use of flash sterilization. The Medical Center also reported an additional \$100,000 had been utilized to purchase new podiatry equipment and instruments to address the demand in the clinic.

The Infectious Disease Program Office (IDPO) reviewed SPD in November 2008, and with the exception of those recommendations that require space consideration, all of the recommendations have been implemented.

Over the last year, Medical Center leadership has acted to improve SPD by recruiting a Chief, and Assistant Chief and six SPD staff positions. They established a quality manager position to oversee SPD, and developed policies for critical, semi-critical, and non-critical reusable medical equipment. Leadership also developed a RME Quality Oversight Committee within SPD to review instrument incidences in the OR Committee, and instituted RME Leadership rounds.

When oversight for the components of SPD that pertained to processing of reusable medical equipment and storage of sterile supplies was moved from Acquisition and Materiel Management under VHA to the Infectious Diseases Program under Patient Care Services (PCS) in VHA, SPD materials were moved from the Acquisition and Materiel Management Web site and temporarily housed on the Web site of VHA's Office of Occupational Safety and Health (OSH). At that time PCS was not able to accommodate the need for an SPD Web site. Acquisition and Materiel Management strongly requested that the SPD information be removed from their Web site, and OSH permitted the temporary housing of the SPD material to allow for continued access to such material by VHA Medical Centers. When SPD was under Acquisition and Materiel Management, a SPD Advisory Group, with members from the Medical Centers was established to generate SPD SOPs to be used as a guide for facilities to develop their own SOPs on a variety of topics. Prior to the listing of these SOPs on the Web site, there is a note that states: "These SOPs are developed as a guide for the starting point of your local SOPs. They must be customized to detail the procedure locally. Local procedures must be signed and approved at the facility. Also at no time will a SOP be written or followed to violate policy." Therefore, the SOP numbered 3003 and titled Instrument Care and Handling is only a guide and not a requirement. The guide can be used by facilities as a starting point and customized as applicable at the local level. VHA has some national policies that pertain to processing of RME, as well as local policies that are approved by leadership and addresses principles as outlined in SOP 3003. The Medical Center has its policies and SOPs that are facility/equipment specific.

Site Visit Findings

Cardiac Catheterization Laboratory (Cath Lab)

The Cath Lab uses sterile instruments on a daily basis. An examination of instruments from the cath lab's storage area revealed no outdated or dirty instruments. The technicians, nurses, physician, and resident interviewed had no concerns about the instruments they receive from SPD.

Ear Nose Throat (ENT)

ENT uses and reprocesses their own scopes; however, they rely on SPD for sterile instruments, reporting any shortcomings to the Chief of Surgery and the Patient Safety Manager. In February of this year, ENT reported a lack of properly sterilized and peel packed instruments, a lack of properly sterilized instruments for an entire week, requiring them to use disposable instruments and to scramble to get needed instruments from other sources. They estimated that there were 10 – 12 incidents over the last year.

On August 13, 2009, in OR Suite 2, a rigid metal lumen suction tube was found to have debris in it, causing contamination of the sterile field. The tube was removed and a new sterile field was established with new equipment. A second tray was readily available, so there was no delay in surgery. In addition, the instrument tray with the dirty tube was mislabeled "OR. Ridig Esophagoscopy Ridig Scope." It should have read "Adult Esophagoscopy Set." ENT has also received sterile OR instrument trays with the wrong expiration dates as well as missing instruments.

The nurses and physician in ENT deny using trays of unsterile instruments. Due to their recent experience they are vigilant about examining instruments prior to use. No one interviewed could verify that they observed nurses in ENT using unsterilized instruments. It should be noted that ENT also uses equipment that comes in touch with the skin that does not require sterilization.

Because SPD staff are required to sign the instrument trays they prepare, the individual who prepared the sterile instrument trays for OR Suite 2 has been identified as (b) (6) (b) (6) and nursing leadership is proposing disciplinary action in the form of a 14-day suspension.

Respiratory

The respiratory department does not use instruments requiring sterilization by SPD.

Genitourinary (GU)

GU has one cystoscope which is reprocessed within their department while biopsies are being done. Although the staff was proud that the scope had not broken down, they had no contingency plans if it did break down. GU has purchased 10 additional cystoscopes, which arrived during this site visit. They do not use sterile instruments from SPD.

Gastrointestinal (GI)

The gastrointestinal section does not use instruments requiring sterilization by SPD.

Operating Room-Post Anesthesia Care Unit (OR-PACU)

The OR has issues with dirty instruments about once a month. The nurses there are observant enough to notice such defects before operations are performed, submitting patient incident reports to nursing for each instance. SPD is also contacted directly to discuss this issue and the OR Committee addresses all incidents of dirty instruments. The OR sometimes receives sterile instruments in packs with no expiration date, the incorrect expiration date, or broken wrappers. Incomplete instrument sets have also been an issue, but this has improved. The nurse manager indicated that staff normally double glove, so the susceptibility to infections is minimal. Flash sterilization is rarely required or used. The PACU uses disposable instruments/equipment. There were also incidents where a glidescope blade and a camera were melted during reprocessing.

Medical and Surgical Intensive Care Units

The intensive care units receive and use instruments sterilized by SPD. The staff interviewed, including a physician, residents, and nurses, indicated that they had no issues with instruments processed by SPD.

Radiology/Vascular Procedure Suite

Radiology uses relatively few instruments from SPD, but will need to develop a standard operating procedure for pre-cleaning the ones they use. The Ultrasound Vaginal Probe is reprocessed in the examination room after patients have been seen. If they had more room, separating the functions of examination and pre-cleaning would be ideal, but overall there were no complaints with general sterilization. The room lacks a timer and a sterilization logbook for start and stop times. They are getting both.

Ophthalmology

This department has four full-time ophthalmologists, three residents, and no optometrists. On occasion, ophthalmology has received damaged equipment from SPD. They cannot see the damage except under magnification. They would prefer to have one SPD technician handle their instruments. All tonometers are disposable. They perform reprocessing of contact lenses in their department, tips for A and B scans, probes and diagnostic lenses. Staff members have portable timers that attach to their belts and demonstrated required competencies to support the management of cleaning and reprocessing RME and instruments. The physician staff competencies are validated by SPD staff that have proven competency in the RME process. Gonio lenses are kept in wooden boxes that cannot be sterilized.

Radiation Therapy

Radiation therapy uses a Zisper clamp which is pre-cleaned and sent to SPD. The staff had no issues with the sterilization of the clamp by SPD.

Dental

Dental uses many metal instruments sterilized by SPD. Staff was very complimentary of the service and sterilization of their instruments. The dentist, the dental assistant, and the dental assistant supervisor all indicated that they would allow the use of instruments processed by SPD on themselves or their family.

Orthopedics

Orthopedic clinic does not use instruments from SPD except for wire cutters which do not come into contact with patients. Orthopedics uses sterile instruments in the OR and does have concerns about the processing of drill bits.

Podiatry

Two contract podiatrists have worked for the Medical Center one day a week; one from January 1993-June 2009, and the other February 1998-June 2009. The Medical Center hired a full time podiatrist in 2006 and a second one sometime later. In 2006, the Chief of Surgery received e-mails from the full-time podiatrist expressing concerns that instruments were not being sterilized, and were being wiped off between patients by the contract podiatrists. An investigation by the Chief of Surgery discovered that instrument trays for podiatry were sterilized, but contained an insufficient number of nail nippers. These nail nippers were being wiped off between patients in the clinics. This practice was immediately halted and additional instruments purchased. Later that year, the same podiatrist complained that dirty, rust-stained instruments were being sent to

the clinic. The Infection Control Nurse cultured the instruments. They were negative for organism growth. The company representative determined that the stains were a build up of calcium. SPD now closely monitors podiatry instruments after sterilization.

Interviews with the podiatrists revealed that at one point things had improved, but problems with blood, and rust-stained instruments has recurred. The investigative team removed five instruments from the podiatry cabinet and found two with what appeared to be dirt/particles on them. All five of the instruments were stained.

The Medical Center has determined that the type and quality of the instruments purchased for podiatry may also contribute to this recurring problem. Instruments purchased for surgery are a higher grade of stainless steel than those in podiatry. In addition, somehow disposable instruments are sent to SPD and get reprocessed and are visibly discolored. Another contributing factor is possibly the well water supply. Recently the Medical Center built a water tower to reduce the mineral buildup on the instruments.

The team contacted the Medical Center following the site visit with some follow-up questions: With regard to how long did the contract podiatrists wipe instruments between patients, the initial response was the entire time that they practiced at the Medical Center. On October 27, 2009, the team received the following response after the Medical Center contacted the contract podiatrists in their private practice: "is that prior to 2006, podiatry nippers that had blood products on them were sent to SPD for sterilization. Those nippers that had no signs of blood products were wiped off and placed in a container of high level disinfectant (Cidex) for 20 minutes to kill organisms." This is inconsistent with what we were told during the site visit and as described in the OSC complaint. The team did not interview the contract podiatrists because they no longer work at the Medical Center.

Dermatology

Dermatology uses disposable instruments 99 percent of the time. On rare occasions they may require sterile instruments from SPD. The physicians and nurse practitioner in the clinic stated that on these occasions, instruments have been sterilized appropriately.

Emergency Room (ER)

The team found the ER busy and left to avoid disrupting patient care. An interview was conducted with the Chief of ER, who indicated that neither he nor the other physicians in the ER have found issues with sterile instruments. They are always appropriately sterilized.

SPD

The physical constraints of the preparation, sterilization, and decontamination areas do not lend to an efficient work flow. The staff in decontamination demonstrated their technique for handling of instruments and articulated the proper cleaning solution that was being used. Decontamination is staffed by three people. During the demonstration by the two SPD technicians, brushing and scrubbing of instruments occurred above the water level, when it should be below water. A contributing factor could be that the sink is extremely low and required constant bending over to accomplish this task. There is no cross training of SPD staff between decontamination and preparation. Each preparation station is equipped with magnified lights that are used by the staff to examine surgical instruments for bioburden/debris. They also indicated that they examine all instrument trays and peel packs after they are removed from the sterilizer, prior to being stored or sent to various departments. Any compromises to the packaging or bioburden/debris seen in the peel packs would require reprocessing and re-sterilizing the item(s).

Summary

The issues with SPD and the reprocessing of RME has been a long-standing concern at the Medical Center. Complaints have been filed with Medical Center leadership, the OIG, and the Office of Special Counsel. These concerns include the inadequate reprocessing of instruments and the exposure of patient and staff to blood-borne pathogens. Several actions have been taken, including review, investigations, consultations, purchase of additional instruments, etc.; however, these issues continue to surface. The investigative team recommends that more focus be placed on the SPD department and its staff. The SPD needs an experienced Chief, Assistant Chief, Supervisor and lead technician who understand the operations and requirements of SPD; all staff in the SPD should be fully trained and in-services on RME and other SPD issues be provided to this staff on a regular basis, preferably on a monthly basis. The physical constraint and lack of cross trained staff would make it extremely difficult to move all of RME to SPD to be reprocessed properly.

Conclusions Based on the Following Allegations

1. For five years doctors and staff at the Medical Center did not follow Occupational Safety and Health (OSH) Standard Operating Procedure (SOP) 3003 when they failed to sterilize medical instruments. Instruments are used on patients for procedures including minor surgery and then merely wiped with a Sani-Wipe and re-used on the next patient. Staff received clean instruments that actually had dried blood on them and/or sterile instruments that were not individually bagged to preserve sterilization. Staff regularly exhausts their

supplies of clean instruments before they are finished seeing patient, and choose to reuse instrument to see more patients.

Although the Medical Center does follow guiding principles outlined in OSH SOP 3003 and have taken several steps to improve the SPD's reprocessing of RME, there are still incidents of dirty, rust-stained instruments being sent to the clinics and operating room. However, thanks to the keen observation of staff in these areas, problematic instruments are identified, removed, and replaced prior to procedures or surgery. The team substantiated that podiatrists in the podiatry clinic prior to 2006, did exhaust their supplies of clean instruments before they finished seeing patients and reused instrument to see other patients. This was corrected by the purchase of more instruments and sterilizing instruments after use. VHA conducted a Pre-Clinical Risk Assessment Advisory Board to determine whether this practice posed a risk to patients treated prior to 2006 and deemed the risk to patients as negligible.

2. In the Ear, Nose, and Throat Clinic (ENT Clinic) nurses have been observed using trays of unsterilized instruments.

The team did not substantiate that the nurses in the ENT clinic have used trays of unsterilized instruments.

3. Staff received sterile instruments that actually have dried blood on them or sterile instruments are not individually bagged to preserve sterilization.

The team substantiated that staff sometimes receives instruments that have been sterilized that have dried blood or other debris on them or that have problems with sterile packaging, with missing instruments, and are mislabeled. Although the issue remains, the facility is aware of it and is addressing it through the OR and Reusable Medical Equipment (RME) Quality Oversight Committees and as stated above, these instruments are identified, removed, and replaced prior to procedures or surgery.

4. The lack of sterile instruments has led to patients and staff being exposed to infectious viruses and bacteria on a regular basis. As a result, thousands of veterans (many of whom have compromised immune systems) have potentially been exposed to a wide variety of infectious viruses and bacteria without their knowledge including: Human Immunodeficiency virus or HIV, hepatitis, methicillin-resistant staphylococcus aureus (MRSA), bacterial-fungal, infections, and warts. Veterans have not been notified of their possible exposure or tested for any infection that may be a result of such exposure.

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immunodeficiency virus, hepatitis, methicillin-resistant staphylococcus aureus, bacterial-fungal infections or warts.

5. Management officials are aware of this continuing public health danger but have taken no action to address the problem.

Over the last several years, management has been acutely aware of the issue with SPD and reusable medical equipment and has taken many actions to resolve it.

Violation/apparent violation of regulations, directives or policies

The VHA team finding regarding violation/apparent violation of regulations, directives, or VAVHA policies is that there are occasions when staff violate policy by failing to ensure that RME are properly cleaned and sterilized.

VHA concurs with findings and will follow up with the Medical Center to ensure full compliance.

Actions Taken/Planned

1. The Medical Center will continue to examine the issues with RME in podiatry to determine why this section continues to have issues with their sterile instruments, i.e. quality of instruments purchased, elimination of reprocessing disposable instruments, appropriate use of chemicals in decontamination, appropriate use of the sterilizers, etc.

Status

Evaluation of podiatry instruments is ongoing. A different type of instrument is being purchased. The chemicals used in the washer are being evaluated. A podiatrist has been added to the leadership rounds and Oversight Committee. The Medical Center has hired a quality manager for RME.

2. The Medical Center will hire, as planned, an experienced Chief and Assistant Chief of SPD and six FTE that are being recruited as soon as possible.

Status:

Recruitment is underway for a Chief, SPD.
An Assistant Chief, SPD has been hired.
Recruiting/hiring six FTE

3. The Medical Center will take immediate actions to assess the learning needs of and provide training to staff in SPD to eliminate/minimize the errors that are occurring with

RME reprocessing. Level 2 certification of staff should be encouraged and regular in-services to assist staff in obtaining/maintaining certification should be instituted immediately.

Status

Several training courses have been conducted for the staff in SPD.

4. Ophthalmology will store their Gonio lenses in a container that can be cleaned effectively.

Status

The container has been ordered and is in use.

5. The Medical Center will cross-train and rotate staff between decontamination and sterile preparation areas to maximize support to SPD. The Medical Center will also ensure that training is provided by a competent instructor, that there is a training record for each SPD employee that documents all training, certificate and/or certification.

Status

Cross-training has been completed and staff is rotated between decontamination and sterile preparation.

6. A VHA Clinical Risk Assessment Advisory Board (CRAAB) will be convened to assess the risk to podiatry patients seen by the contract providers prior to the change in practice that occurred in 2006, i.e., the purchase of adequate numbers of instruments that allowed for appropriate sterilization after each individual patient use, for exposure to blood borne pathogens. If patients are found to have exposure to blood borne pathogens, disclosures will be made in accordance with VHA Directive 2008-002, Disclosure of Adverse Events to Patients, and the appropriate treatment provided.

Status:

A Pre-CRAAB was convened and determined that the risk to patients was negligible.

7. Management will continue its efforts to improve SPD, through hiring as timely as possible and through close oversight of compliance of the following:

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

b. VHA Directive 2009-031, Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements, June 26, 2009.

c. VA Handbook 7176, Supply Processing and Distribution, August 16, 2002.

Status

Management has continued oversight through: leadership rounds, the RME Oversight Committee, and the OR Committee.

8. Until the appropriate SPD leadership is in place and the needed SPD training is completed, the Medical Center will not realign any further RME processing to SPD from areas where reprocessing activities are currently appropriately managed outside of the central SPD department.

Status

No additional RME reprocessing has moved to SPD.

ATTACHMENT C



U.S. Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

DEPARTMENT OF VETERANS AFFAIRS REPORT SUBSTANTIATES VA MEDICAL CENTER FAILED TO PROPERLY SANITIZE INSTRUMENTS

FOR IMMEDIATE RELEASE

CONTACT: Darshan A. Sheth, (202) 254-3617; dsheth@osc.gov

WASHINGTON, DC / October 21, 2010 – Today, the U.S. Office of Special Counsel (OSC) transmitted to the President and Congressional oversight committees findings of a Department of Veterans Affairs (VA) investigation confirming that improperly cleaned and poorly sanitized instruments were distributed to clinics and operating rooms at the VA's G.V. (Sonny) Montgomery Medical Center (Jackson VAMC) in Jackson, Mississippi.

OSC received these allegations from a whistleblower and referred them to the Secretary of the VA for further investigation. The report of that investigation, which was conducted by the Veterans Health Administration (VHA), confirmed that dirty and rust-stained instruments, such as scalpels, blade handles, tissue and nail nippers, hemostats, and bone cutters, were issued for use within the Jackson VAMC. The report noted that generally, on occasions when dirty instruments were distributed, staff discovered them prior to use and replaced them with clean instruments. The report also stated that prior to 2006, providers specifically in the Jackson VAMC podiatry clinic experienced frequent instrument shortages, resulting in the reuse of unsterilized instruments. The agency stated that this problem was resolved by the purchase of additional instruments.

In response to the sterilization problems that the investigation identified within the podiatry clinic, the agency convened a Pre-Clinical Risk Assessment Board (Pre-CRAAB) to determine whether the possible exposure to veterans prior to 2006 required that notice be given regarding possible infection. The Pre-CRAAB was comprised of VA staff from VA headquarters in Washington, D.C. and local staff from the Jackson VAMC. The Pre-CRAAB determined that the risk to patients was negligible and that notice was not required.

In response to these allegations, the agency pledged to follow up with the Jackson VAMC to ensure full compliance with proper cleaning and sterilization processes hospital-wide. The Jackson VAMC also committed to paying close attention to equipment issues within the podiatry clinic, and to purchasing a new type of instrument and evaluating the chemicals in the instrument washer to ensure cleanliness. A podiatrist was added to both leadership rounds and the Reusable Medical Equipment (RME) Oversight Committee and a quality manager was hired for RME. In addition, the Jackson VAMC began the hiring process to fill the positions of Chief and Assistant Chief of Supply, Processing, and Distribution (SPD)

Section, the section responsible for cleaning and sanitizing instruments, as well as six Full-Time Equivalent SPD support positions. The hospital also pledged to assess the learning needs of current SPD staff and to provide them with training and assistance in achieving certification.

OSC determined that the agency's report contains all the information required by statute and the agency's findings appear reasonable. However, OSC noted with concern the whistleblower's comments that the Jackson VAMC continues to distribute instruments which have not been properly cleaned and sterilized. OSC also expressed its concern that the Pre-CRAAB process, as described by the agency, could be compromised by the involvement of management officials who are potentially directly responsible for allowing the underlying conduct to continue.

The U.S. Office of Special Counsel (OSC) is an independent investigative and prosecutorial agency and operates a secure channel for disclosures of whistleblower complaints. Its primary mission is to safeguard the merit system in federal employment by protecting federal employees and applicants from prohibited personnel practices, especially retaliation for whistleblowing. OSC also has jurisdiction over the Hatch Act and the Uniformed Services Employment and Reemployment Rights Act. For more information please visit our web site at www.osc.gov or call 1 (800) 872-9855.

ATTACHMENT D



**G.V. (Sonny) Montgomery VA
Medical Center
1500 Woodrow Wilson Drive
Jackson, MS 39216**

News Release

**For More Information
Contact:
Mario Rossilli
Phone: (601) 368-4477
Cell: (601) 421-8266**

October 21, 2010

Statement Regarding Podiatry Reusable Medical Equipment (RME) Report

The report regarding the cleaning of Reusable Medical Equipment (RME) in podiatry concluded that the Jackson VA Medical Center was compliant with all VA regulations, rules and procedures.

The VA report focused on podiatry from 2001 to 2006 and on the use of nippers (nail clippers). Nippers used for treatment were disinfected. VA followed the cleaning standard at the time.

As a result of the report, VA conducted a review which included the use of an outside specialist of all patients seen between 2001 and 2006 who were treated with nippers. No patients had any infections related to their podiatry procedures. No patients were treated with improperly cleaned equipment according to the standard of care at the time.

The Medical Center had in place an extensive system of checks and balances for all medical equipment. As the Office of Special Counsel news release points out, in some cases, equipment that was not appropriate for use was found by staff during these checks and balances. Such equipment was not used and at no time was any Veteran exposed to infectious material.

Since the report, the Medical Center now sterilizes nippers – exceeding the standard for reuse. In addition, the Medical Center now conducts extensive rounds of its Supply, Processing and Distribution (SPD). SPD is reviewed daily by a Quality Management Specialist, weekly by the Quality Management Office, and monthly by the Medical Center Executive Leadership Team.

The Jackson VA Medical Center is committed to ensuring the safety of the men and women who served our nation in the armed forces. Recently, the National Center for Patient Safety recognized the Medical Center's Patient Safety Program with a Silver Cornerstone Award for its efforts to enhance patient safety.