THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON
November 15, 2011

The Honorable Carolyn Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M. Street, N.W., Suite 300
Washington, D.C. 20036-4505

Re: OSC File No. DI-11-2518

Dear Ms. Lerner:

Enclosed is the Department of Veterans Affairs' (VA) report in response to your request of July 1, 2011, to investigate allegations that VA employees at the G.V. (Sonny) Montgomery Veterans Affairs Medical Center in Jackson, Mississippi, failed to properly wear personal protective equipment (PPE) in the decontamination area of the Sterile Processing Department (SPD), misrepresented to investigators the numbers and types of reusable medical equipment reprocessed in the facility, and failed to properly train Medical Supply Technicians. On August 18, 2011, my staff requested an extension to the September 6, 2011, deadline and then verbally briefed your office on the status of this investigation on August 30, 2011. You then requested that VA provide a draft report to substantiate the information provided in the briefing. Because the draft report had not been approved by me, it was not appropriate to release the draft. The enclosed report is VA's final report in response to these allegations.

A team from the Veterans Health Administration investigated these allegations and substantiated that employees within the decontamination area of the SPD failed to properly wear PPE, though this violation of Agency policy did not endanger patients. Local management took immediate corrective action. However, as detailed in the attached report, the investigatory team did not substantiate the remaining allegations.

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

Sincerely,

Eric K. Shinseki

Enclosure

OSC File Number DI-11-2518, Jackson, Mississippi

I. SUMMARY OF INFORMATION

The Veterans Health Administration (VHA) investigated allegations made to the Office of Special Counsel (OSC) by the complainant, a former Chief Intern in the Sterile Processing Department (SPD) from May 2009 to May 2011 at the G.V. (Sonny) Montgomery Veterans Affairs Medical Center, Jackson, Mississippi (Medical Center). The complainant alleged that employees engaged in conduct that may constitute violations of law, rule, or regulation, gross mismangement, an abuse of authority, and a substantial and specific danger to public health. The complainant made three general allegations:

1. Medical Supply Technicians (Technicians), who are the employees responsible for reprocessing (i.e., cleaning) reusable medical equipment (RME), failed to follow Agency policy regarding the wearing and use of personal protective equipment (PPE) in the SPD decontamination area.

2. Medical Center management misrepresented to investigators the numbers and types of RME reprocessed by SPD and interfered with investigations.

3. Medical Supply Technicians are not properly trained on the reprocessing of RME.

II. CONDUCT OF THE INVESTIGATION

The Investigation Team (Team) notified the Medical Center Director of the complaint and of its plans for an August 23 – 25, 2011, site visit. The Assistant Director for Quality Management coordinated the visit, and the investigators received full cooperation from the Medical Center staff. The Team consisted of the Acting Director, National Office for Sterile Processing; a Sterile Processing Site Reviewer; and the Clinical Program Manager for the Office of the Medical Inspector.

After holding an entrance briefing with the Medical Center leadership, the Team interviewed staff from the following areas: Sterile Processing, Office of Quality Management, Office of Nursing Service, Operating Room, and Chief of Surgery. The former Medical Center Director has retired from Federal service and was not interviewed. The following is a list key individuals who were interviewed by the Team:

Associate Director for Patient Care Services;

Acting Chief of SPD;

Assistant Chief of SPD;

Quality Management Analyst;

two Veterans Integrated Service Network (VISN) Inspectors; and

Complainant, a former SPD Chief Intern.

The Team reviewed the following documents:

Records of RME;

Staff Training Records;

Staff Inservice Records;

Staff Competencies;

Standard Operating Procedure Manuals; and

Manufacturers' Instructions for Use.

At the conclusion of the site visit, the Team held an exit briefing with the Medical Center Director, VISN Director, and VISN Chief Medical Officer.

III. SUMMARY OF EVIDENCE

Allegation #1: Medical Supply Technicians (Technicians), who are the employees responsible for reprocessing (i.e., cleaning) reusable medical equipment (RME), failed to follow Agency policy[1] regarding the wearing and use of personal protective equipment (PPE) in the SPD decontamination area.

Findings:

The decontamination area is the room within SPD in which RME receive its initial cleaning after use. There is a wall that separates the decontamination area from the preparation area, which is the area in which RME receive final packaging and sterilization prior to return into circulation. Technicians who clean RME in the decontamination area do so by placing the RME in a washing decontaminator whose exit is located in the preparation area. Thus, it is not possible for patients to be placed at risk if items such as earrings, watches, and cell phones are brought into the decontamination area. Rather, the rationale behind regulating what Technicians wear within the decontamination area is to protect the Technicians and their property.

An unannounced visit to the SPD decontamination area was conducted on August 24, 2011. At that time, the Team discovered one employee in the decontamination area without face covering or gloves. The two employees working in the area were both wearing their protective gowns inappropriately. When questioned why the gowns were on backwards, both replied that this is the way they were taught to wear them. The Team then met with the Assistant Chief of SPD, who also placed her gown on backwards. She too stated that this is the way she was taught to wear the gown. The Lead Investigator then conducted an on-the-spot inservice training (inservice) on how to wear the gown properly. The Assistant Chief of SPD conducted a documented

[1] The July 1, 2011, OSC letter references VHA Handbook 7176. Please note that the proper reference, used throughout this report, is VA Handbook 7176.

inservice for the department the following morning. SPD leadership then counseled the employees, in writing, regarding the proper use of PPE.

The complainant specifically alleged that Technicians failed to wear proper face coverings and gloves in the decontamination area. Based upon the site visit, the Team substantiated that Technicians did not, at all times, properly wear PPE. The Team noted that the failure to properly wear PPE created risk to the Technicians, but not to patients.

The complainant alleged that Technicians wore hoop earrings and watches in the decontamination area, and brought cell phones into the decontamination area. The Team did not substantiate that employees wore hoop earrings or watches in the decontamination area, though one Technician stated that she wore hoop earrings to work but left them in her locker while at work. The Team also did not substantiate that employees wore watches in the decontamination area or brought cell phones into the decontamination area. Further, cell phones are not addressed in *VA Handbook 7176*. Even if Technicians committed the acts alleged by the complainant, this could have not have endangered patients.

The complainant also alleged that Technicians frequently donned their PPE after entering the decontamination area and that they retrieved outergarments from within the decontamination area and wore them throughout the Medical Center. The Team did not substantiate that Technicians frequently donned PPE after entering the decontamination area. The decontamination area has an anteroom for personnel to dress in PPE prior to entering into the decontamination area. All required PPE was located in the anteroom. The Team did not substantiate that Technicians retrieved outergarments from within the decontamination area and wore them throughout the facility. There are designated coat hooks in the anteroom with lab coats for employees to wear over their scrub suits after removing their PPE. This is a common and accepted practice. Again, even if Technicians committed the acts alleged by the complainant, this could have not have endangered patients.

The complainant also alleged that Technicians wore proper PPE only during VISN and VA Central Office inspections. However, the Team discussed this allegation with management and confirmed that it was common practice to reinforce the correct wearing of PPE at all times, not just during VISN and VACO inspections.

The complainant also alleged that she notified facility leadership of her concerns regarding the proper use of PPE, but that her concerns were ignored. The Team, however, was provided a copy of the email that the complainant sent to management officials. The Team also substantiated that the Associate Director for Patient Care Services forwarded the email to the Assistant Chief of SPD for further action, which resulted in SPD conducting multiple inservices regarding the proper use of PPE.

Allegation #2: Medical Center management misrepresented to investigators the numbers and types of RME reprocessed by SPD and interfered with investigations.

Findings:

The complainant alleged that facility leadership made misrepresentations and interfered with investigations on two occasions.

On July 29, 2010, there was a VISN inspection of SPD. The complainant alleged that VISN inspectors asked whether the SPD binder had manufacturers' instructions for all RME and that the complainant, after reviewing the SPD binder, answered that the binder was not complete. The complainant alleged that the VISN inspectors then asked the Assistant Chief of SPD, the same question and that she replied that the binder was complete. The complainant alleged that her statement was a misrepresentation. After questioning the Assistant Chief of SPD, the complainant, and a Quality Assurance Specialist who was present during this exchange, the Team substantiated that this exchange occurred, but that there was no evidence that the binder was not complete. Both the Assistant Chief of SPD and the Quality Assurance Specialist stated that the binder was complete.

The complainant further alleged that following this exchange, one inspector asked the complainant if she had another document containing the list of RME, and that the complainant printed the list and emailed it to the inspectors (OSC Enclosures 1 and 2). However, the complainant alleged that when she attempted to bring the list to the inspectors, the Associate Director for Patient Care Services was in a meeting with the inspectors and that she, after leaving the meeting, took the list from the complainant and stated that the inspectors did not need the list. The complainant alleged that on the following day, the Associate Director for Patient Care Services created an "alternate" list of RME that excluded approximately 23 pieces of RME and misled the investigators by providing this incorrect list (OSC Enclosure 3). The Team did not substantiate these allegations. The Associate Director for Patient Care Services testified that the complainant provided her with what the complainant thought was a complete list of RME, but that the Associate Director for Patient Care Services informed the complainant that the list that she had was an inventory assignment—not the complete list of RME. The Associate Director for Patient Care Services testified that the complainant said "OK," gave the list to her, and walked away.

The complainant's main allegation, however, is that the Associate Director for Patient Care Services later compiled an incomplete list of RME for the inspectors. The Team compared this list (OSC Enclosure 3) with the RME lists on-station and found that the records matched. The Team also compared the items listed on OSC Enclosures 1 and 2 (what the complainant alleged to be the complete lists of RME) with the items listed on OSC Enclosure 3 (what the complainant alleged to be the incomplete list compiled by the Associate Director for Patient Care Services). The Team found that all pieces of equipment alleged to be missing from Enclosure 3 are, in fact, listed in Enclosure 3, with the exception of one piece of equipment (an Olympus SIF-H180, (EGD) Small Intestine Video Scope) that is not listed on Enclosure 3 because it was no longer in use at the facility. Thus, Enclosure 3 is an accurate listing of facility RME and was not a misrepresentation.

The second occasion of alleged improprieties was in response to OSC File No. DI-09-3272, when the Agency sent investigators to the Medical Center in October 2009. The complainant alleged that after she was questioned during this investigation, the Associate Director for Patient Care Services asked the complainant what questions were asked by the inspectors and how the complainant responded. The Associate Director for Patient Care Services then allegedly told the complainant to give this information to the former Medical Center Director. The Associate Director for Patient Care Services then allegedly asked the complainant to draft a memo about the contents of the interview.

The Team did not substantiate these allegations. The Associate Director for Patient Care Services denied asking anyone to document their conversation with investigators. She informed the Team that she did not ask the complainant to come to her office following the complainant's interview with the investigators. Rather, the complainant came to the Associate Director for Patient Care Services' office and informed her that the former Medical Center Director had directed the complainant to write down what questions the investigators asked and the complainant's responses. The Associate Director for Patient Care Services said that she asked the complainant whether she had done so, and that the complainant replied that she had not. The Associate Director for Patient Care Services also denied that she directed the complainant to inform the former Medical Center Director of the contents of the interview. The Associate Director for Patient Care Services also denied asking the complainant to draft a memorandum outlining the contents of the interview. Further, the complainant could not provide the Team with a copy of this alleged memorandum.

The complainant also alleged that the Associate Director for Patient Care Services and the former Medical Center Director assigned facility employees to shadow investigators. The Team substantiated that this occurred, but that it is common practice at Medical Centers to assign personnel from Quality Management, Facilities Management, the Director's Suite, or other departments to assist investigators. This requires the employees to accompany investigators and to take notes and in no way constitutes interference with an investigation. On the contrary, such practice is an encouraged management technique that allows facility leadership to take immediate corrective action without waiting for the investigators' report or out-briefing.

Allegation #3: Medical Supply Technicians are not properly trained on the reprocessing of RME.

Findings:

The Team did not substantiate that Medical Supply Technicians are not trained in proper techniques for reprocessing each piece of RME. A review of the SOP Binders and Competencies demonstrated that inservices were conducted for each specific piece of equipment and competencies were signed for each Technician who attended the inservice. Further, a review of training records shows that all new employees completed Level I SPD training as required by *VA Handbook 7176.* Personnel are routinely assigned to a senior staff member when working in the various areas during orientation. The Team also did not substantiate that problems in SPD continued for

approximately one year after the agency assured OSC that corrective actions were taken and continuing oversight was in place following OSC Investigation File No. DI-09-3272. Rather, the Agency hired a new Chief of SPD, an Assistant Chief of SPD, and 13 new staff since January 2011. Multiple inservice education sessions are documented showing a pattern of continued training for staff.

The Team spoke with the Operating Room Nurse Manager and the Chief of Surgery, who expressed high confidence in the Sterile Processing Department. In fact, the Team learned of only three instances since October 2010 in which instruments were returned to SPD from the Operating Room, and none of the instances were based upon a Technician's failure to properly follow manufacturers' instructions. The three incidents involved orthopaedic equipment sets. There is an inherent problem with these sets as small bone fragments can lodge in hard-to-find places such as drill bits and become dislodged during the sterilization process. Often the dislodged fragment will fall to the bottom of the equipment tray, underneath the piece of equipment, where it is difficult to detect. In each instance OR staff identified the problem and returned the instruments to SPD prior to beginning the medical procedure. These instances do not represent a routine failure when compared to the number of sets processed on a daily basis, and considering the fact that these sets can contain between 500 and 1,000 pieces of equipment. They do, however, warrant continued scrutiny of the reprocessing of orthopaedic sets. Further, the Team noted that the problem of bone fragments in reprocessed orthopaedic sets is related to the design of the equipment and occurs in all medical facilities, not just VA facilities.

The Team found that surgical sets are routinely inspected by two persons on the preparation side of SPD and that their signatures are attached to the count sheets accompanying the set to the Operating Room. The Team stressed to management the need for continued close inspection of equipment trays following reprocessing.

IV. SUSTAINED VIOLATIONS

The Team found no violation of law, rule, or regulation. However, the team did find non-compliance with VA directives.

V. ACTION TAKEN

1. Immediate inservice corrective training was conducted when the Team discovered SPD personnel improperly wearing PPE.

2. Management immediately counseled employees who were improperly wearing PPE.

3. The Medical Center will continue to monitor PPE use in the decontamination area and continue to train SPD personnel on proper use of PPE.

4. SPD leadership will continue to stress thorough visual inspection of equipment trays following RME reprocessing.