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The Special Counsel

July 30, 2014

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-13-2133

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), enclosed please find agency reports based on disclosures made by a whistleblower at the Department of Veterans Affairs (VA), Ann Arbor VA Medical Center (Medical Center), Ann Arbor, Michigan. The whistleblower, Larry Ludtke, Jr., disclosed that employees were engaging in conduct that may constitute violations of law, rule, or regulation and gross mismanagement, which could lead to a substantial and specific danger to public health. Mr. Ludtke, who consented to the release of his name, was employed as a medical supply technician. He alleged that employees consistently failed to follow proper procedures in the decontamination and sterile storage areas, and that patients and staff were at risk of infection from contaminated supplies and equipment.

The agency investigation, conducted by the Office of the Medical Inspector (OMI), substantiated several of Mr. Ludtke's disclosures, finding that employees were not properly trained in safety and conduct requirements. The investigation also found that employees violated procedures to protect against contamination of sterile supplies and equipment. Despite this finding, the agency investigation did not reveal evidence of contamination as a result of the employee non-compliance. The agency reports identified the corrective actions taken at the Medical Center in response to the investigation, including renovations to improve functions in the supply and processing divisions. OMI provided a summary supplemental report on the status of the corrective actions. All of the twelve recommendations were adopted, nine have been completed, and three are ongoing. Despite my request, the OMI declined to investigate the whistleblower's more recent, specific allegations regarding compliance with safety procedures. Based on my review, I have determined that although the agency reports contain all the information required by statute, the findings do not appear reasonable given the whistleblower's ongoing concerns regarding compliance with safety procedures and the agency's decision to ignore these concerns.

The allegations were referred to then-Secretary Eric K. Shinseki on June 18, 2013. Review of the matter was delegated to the Under Secretary for Health, who requested that the OMI investigate the allegations. OSC received the agency's report on September 26, 2013. Mr. Ludtke provided comments on the report, and OSC provided Mr. Ludtke's comments to the OMI, as they outlined continuing concerns regarding the safe processing of equipment. OSC received the agency's supplemental report on May 27, 2014. Mr. Ludtke provided

comments on the supplemental report on June 30, 2014. As required by 5 U.S.C. § 1213(e)(3), I am transmitting the agency reports and Mr. Ludtke's comments to you.[1]

The Whistleblower's Allegations

Mr. Ludtke was a medical supply technician in the Logistics (Material Support Department or MSD) and Sterile Processing Service (SPS) at the Medical Center.[2] MSD supports the operating rooms with surgical case carts and sterile and non-sterile supplies, and the Medical Center with general medical supplies. SPS processes Reusable Medical Equipment (RME). Mr. Ludtke disclosed that MSD and SPS employees lack training sufficient to follow proper procedures. In addition, he alleged that management failed to enforce policies and procedures to ensure the proper processing, sterilization, and storage of medical and surgical equipment. To support his allegations, he referred to the VA's Office of Construction & Facilities Management's Supply, Processing and Distribution Design Guide (Design Guide)[3], and Section 1 of the VA's SPD Training Manual.[4]

Both the Design Guide and the SPD Manual address environmental considerations most critical to SPD, including facility design. The most significant of these considerations are the separation of soiled areas from clean areas, the restriction of certain areas from access by contaminated people and equipment, and the improper use of rooms based on function and staff utilization. Mr. Ludtke also cited the International Association of Healthcare Central Service Materiel Management (IAHCSMM) Central Services Technical Manual, adopted by the VA.[5] Chapter 6 of the Technical Manual describes the need for separation of clean and dirty items and emphasizes the importance of changing into clean attire before beginning work. This would reduce the potential of microorganisms being introduced and would ensure against the transmission of potentially pathogenic microorganisms on clothing when employees leave.

Mr. Ludtke asserted that the facility at the Medical Center was deficient because the entrances and exits to sterile storage areas were not properly controlled, and because the area was too small to meet the appropriate storage requirements. He disclosed that SPS and MSD

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[1] The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c). Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

[2] Mr. Ludtke retired in June 2014.

[3] Department of Veterans Affairs, Office of Construction & Facilities Management Design Guide, *Supply, Processing and Distribution*, Sections 2 and 3 (February 2010).

[4] Department of Veterans Affairs, Supply, Processing and Distribution Training Manual, TP 90-2, Section 1 (2004).

[5] International Association of Healthcare Central Service Materiel Management, Central Service Technical Manual, Chapters 1, 6, 13 and 20, and Figure 6-6 (2010).

male employees shared a locker/shower room on the decontamination (dirty) side of the department. There was no clean men's locker/shower room for employees working in the clean/sterile storage area or the sterile preparation side of the department. Female employees shared clean and dirty locker rooms, and were allowed to choose which room to use. According to Mr. Ludtke, separation of locker/shower facilities is required to prevent cross-contamination.

He also disclosed that the SPD facility did not have the necessary processing in-and-out rooms to permit employees to dress appropriately before entering the secured area. This was partly due to the absence of an ante-room, which supports one-way traffic flow of personnel from clean to dirty. The ante-room for the decontamination area was being used as a break room for employees working in sterile storage, preparation, and decontamination. As such, there was no ante-room for the preparation and sterile storage personnel to process into those areas. According to the Technical Manual and the SPD Manual, the first step in maintaining environmental integrity is controlling the traffic that enters and passes through the central service areas. A dedicated, one-way flow through locker rooms is designed to promote the maintenance of a clean environment in both the MSD and SPS.

Mr. Ludtke also disclosed that certain supplies were stored improperly, potentially exposing them to contamination. He indicated that, due to the facility's space and logistical restrictions, operating room trays and sterile supplies were not stored in an aseptic environment, but were instead stored alongside regular medical supplies in higher traffic areas, and sometimes in a hallway outside of SPD when the storage area was over-filled.

Mr. Ludtke also disclosed that SPS employees ignored safety and conduct requirements, resulting in an increased risk for equipment contamination. He explained that decontamination staff worked on both sides of the cart washer in dirty scrubs and personal protective equipment. Employees loaded dirty sterilization pans on the dirty side, and after they were cleaned, the same employees unloaded the clean pans on the clean side, thereby contaminating the equipment. Employees also wore blue coats specifically meant to be worn for cleaning and decontamination when they left the MSD and SPS departments, potentially contaminating others in the Medical Center.

Finally, Mr. Ludtke noted that policies and training for new and current employees were insufficient to ensure that employees properly processed, sterilized, stored, and transported medical and surgical equipment. He asserted that there were no written policies for any MSD functions, including to address ingress and egress to and from sterile storage, proper traffic flow of staff and equipment, proper handling of sterile products, proper attire inside and outside of sterile storage, entry and exit points for sterile storage, and department cleaning by MSD and Facilities Maintenance staff. He believes that the lack of policies and training for SPS employees resulted in the failures he disclosed.

In early 2011, Mr. Ludtke reported these concerns to the VA's Office of Inspector General (OIG). The OIG completed a site visit and issued an undated report, a copy of which was provided to Mr. Ludtke by Representative Tim Walberg with a letter dated August 30, 2011. The OIG report contained recommendations to address the long-term space utilization

and personnel training problems disclosed by Mr. Ludtke. These recommendations included training employees on appropriate work attire and use of personal protective equipment, and determining whether more training for staff using case carts was warranted. The VA outlined several steps it was taking in response to the recommendations, including a system redesign, re-keying work areas to limit access/flow between areas, and requesting electronic card swipe access and two automatic doors to prevent doors from being propped open. Mr. Ludtke reported that none of the recommendations was implemented.

Mr. Ludtke disclosed that despite the VA's pledge to take the corrective actions identified in response to the report, problems in the decontamination and sterile supply areas continued to occur. Mr. Ludtke identified specific incidents between October 2012 and February 2013 in which employees either failed to wear proper protective equipment, improperly handled equipment, or entered and exited sterile areas while wearing contaminated clothing.

Mr. Ludtke also described gross contamination that occurred in advance of a January 17, 2013 visit by Stuart Pigler, a staff member from the office of Representative Mike Rogers. When notified of the visit, Michael Ruggerio, MSD chief, ordered that the SPD facility be cleaned. Cleaning staff sprayed floor cleaners in the sterile storage room without removing sterile supplies from the shelves. Mr. Ludtke reported that he could see splash marks on the supplies throughout the room, at least eighteen inches vertically from the floor. He also indicated that there were handprints on shelving in the storage area, due to a chalky residue from the cleaners. He indicated that the doors in the pressure-controlled environment were propped open, and the cleaning solution and scrubber pads were used both inside and outside of the room. Mr. Ludtke stated that the proper procedure for cleaning would have been to remove or cover the sterile supplies and equipment to ensure that they were not contaminated with cleaning agents. He reported this to his supervisor, Amy Lyons, chief of Infection Control. She indicated that she "did not see a problem," and she and Mr. Ruggiero authorized the use of the products despite the contamination. The contaminated supplies and equipment were later used for patient care and treatment.

The Agency's Report

The agency's report explained the history of the Medical Center's Department of Sterile Processing and Distribution (DSPD). Before 2009, the DSPD was responsible for medical supply storage and distribution as well as the processing of reusable medical supplies and equipment. According to the report, in 2009, VHA realigned DSPD functions to more clearly emphasize the processing of reusable medical equipment. The portion of DSPD responsible for processing was reassigned to the associate director of Patient Care Services and renamed SPS. The distribution function was reassigned to the Logistics Service and named MSD. In 2010, the Medical Center, in response to increased productivity in the operating room, initiated plans to expand and renovate the SPS area. Given the increase in the number of surgeries performed at the Medical Center over the last five years, the scope of the project was broadened. The final plan, approved by the National Program Office and submitted for funding, includes additional storage space, locker room space, processing space, and additional processing equipment.

The report also outlined the VHA standards, set out in the Medical Center's SOP, as well as professional association standards that are also applicable to the Medical Center. According to those standards, storage areas are designated as clean or dirty. Sterile materials should be stored in a clean environment, with appropriate consideration given to placement on shelving, as well as to the type and placement of the shelving itself.

The agency investigation found that SPS and MSD are co-located at the Medical Center, reflecting the organizational structure prior to 2009. The MSD's current area for supplies is one very large room in which both sterile and non-sterile supplies are stored. The investigation determined that although the room was very full, all supplies were on shelving and met the storage requirements noted above. Because the Medical Center currently has limited storage space pending the approved renovation, MSD was using all available space, including an enclosed corridor, to store supplies. OMI observed non-sterile items stored both above and next to sterile items. According to the report, association standards recommend storing sterile and non-sterile supplies separately. If sterile items are stored in the same area with non-sterile supplies, they should be stored on separate shelves and above the non-sterile supplies.

With respect to the decontamination rooms, OMI observed staff exiting the decontamination area still wearing their personal protective equipment (PPE), which should have been removed in the decontamination area. The decontamination area lacked a PPE disposal container at the exit. OMI observed one staff member remove PPE in the decontamination area, drop it on the floor, and leave to go to the bathroom. One staff member assigned to the decontamination area admitted to entering the clean corridor wearing her decontamination PPE to retrieve supplies, although she also acknowledged being trained to remove the PPE when leaving the area.

The agency report also found that the supervisor responsible for cleaning the SPS and MSD areas during the night shift was not able to articulate the cleaning process, identify the equipment used to clean these areas or the solutions and strengths to use. With respect to Mr. Ludtke's specific allegations that splash marks contaminated the lower shelving in the storage area, the investigation found that after notification of this potential contamination, the supervisor removed affected items, discarded disposable items and sent reusable items for reprocessing.

The OMI reviewed Medical Center data regarding infection rates in patients who underwent surgical procedures, and did not find any adverse outcomes linked to instrument processing, storage, or distribution. Nor did the OMI find any evidence that the current design, training, and enforcement increased the risk of infection to either patients or staff. As a part of its quality improvement program, the Medical Center monitors feedback from end users of the equipment. Specifically, the Medical Center sought feedback from the operating room on the quality of instrument processing, timeliness and availability of instruments and proper assembly of the different trays. During the current fiscal year, the operating room reported seventy-eight incidents of receiving trays with missing, wrong, or damaged instruments, with a monthly average decrease from fourteen to two. The number of incidents

of improperly assembled trays was reported as sixty-one for the current fiscal year, with a monthly average decrease from thirteen to four. No cases were reported delayed or canceled because of SPS or MSD issues. As such, there was no evidence that the current design, training, or enforcement increased infection to either patients or staff.

The investigation also considered eleven specific incidents cited by Mr. Ludtke as examples of the improper practices at the Medical Center. The OMI partially substantiated one incident, did not substantiate a second, and could not substantiate the remaining nine. Of the nine that could not be substantiated, the OMI cited lack of witnesses to the incidents and denials by the employees allegedly involved.

The report made ten recommendations to the Medical Center and one recommendation to the VHA. Recommendations to the Medical Center included: (1) providing additional training for MSD staff on stocking shelves in supply storage; (2) reorganizing storage in the supply storage room to ensure that sterile and non-sterile supplies are segregated; (3) re-evaluating and re-writing the Medical Center's dress policies for restricted areas and simplifying training, enforcement, and monitoring; (4) providing training to SPS and MSD staff on the revised dress policy; (5) retraining decontamination staff members on traffic flow in their section and on appropriate use and discarding of PPE; (6) ensuring appropriate placement of trash receptacles at the decontamination area's exits, and monitoring compliance; (7) sealing the door between the decontamination area and the room outside the locker and restrooms; (8) making the door from the decontamination area into the clean corridor one-way and realigning functions so that employees from the clean supply storage staff are responsible for retrieving the clean carts from the washer for use in preparing case carts; (9) providing training on proper cleaning methods in the SPS and MSD areas to cleaning supervisor and staff, and; (10) providing MSD staff training on removal of suspected contaminated supplies. The recommendations also included monitoring compliance and addressing non-compliance where appropriate. The report recommended to VHA that it consider accelerating funding of the Medical Center's approved SPS and MSD renovation plan to ensure that these services continue to expand to meet the growing demand.

The Whistleblower's Comments

Mr. Ludtke provided comments on the agency report. He identified specific incidents that raised questions about the impact of the corrective actions reported to have been implemented. Although no longer employed in the SPS/MSD divisions, Mr. Ludtke was in the SPS and MSD areas on March 25, 2014. Among other observations, he saw the chief of MSD, Michael Ruggierro, exit the sterile supply area, hand supplies to a customer, and re-enter the area, without wearing proper attire. He also observed that although renovations had begun, barriers to construction were inadequate to prevent dust from entering the sterile processing areas.

On April 16, 2014, OSC provided Mr. Ludtke's written comments on the report to the agency, with a request for a supplemental report addressing the concerns raised in the comments. OSC noted that the whistleblower's concerns related to the impact of some of the

corrective actions taken by the Medical Center based on the OMI recommendations, including ongoing renovations.

Meeting with Medical Inspector

On April 24, 2014, OSC met with then-Medical Inspector Dr. John Pierce, at his request, to discuss the continuing concerns. Dr. Pierce informed OSC that OMI's case was closed and that any further disclosures should be treated as new disclosures and referred for investigation under OSC's procedures. He abruptly terminated the meeting. Subsequently, the agency agreed to provide a supplemental report.

The Supplemental Report

The agency's supplemental report did not address the whistleblower's comments, nor did it reflect that any additional investigation occurred. It reported that nine of the recommendations in the original report had been completed, and that three are ongoing. The three recommendations for which corrective action is ongoing all relate to training and compliance.

The first recommendation was that the Medical Center should retrain decontamination staff members on traffic flow in their section and on appropriate use and discarding of personal protective equipment. Once training is completed, the Medical Center should monitor compliance and address non-compliance. According to the supplemental report, the Medical Center provided training to the SPS decontamination staff about the proper flow of traffic as well as the appropriate use and discarding of personal protective equipment, and is continuing to monitor compliance.

The second recommendation for which corrective action remains ongoing relates to the provision of training to MSD staff on the removal of suspected contaminated supplies. According to the supplemental report, the Medical Center updated the training module, *Introduction to Distribution*, which addresses the removal of suspected contaminated supplies, and trained SPS and MSD staff on its use, including updates. The supplemental report also noted that the new-employee orientation now includes a review of this module.

Third, the OMI recommended that the Medical Center provide training to MSD staff on the removal of soiled supplies from carts. This information is now included in new employee training and compliance continues to be monitored.

The Whistleblower's Supplemental Comments

Mr. Ludtke provided comments on the supplemental report. In the comments, he outlined the timeline of his efforts to correct wrongdoing within and outside the agency. He reiterated his prior concerns and noted that he has requested that OMI shut down sterile processing at the Medical Center until renovations are complete.

The Special Counsel's Findings

I have reviewed the original disclosure, the agency reports, and Mr. Ludtke's comments. The agency has not been fully responsive to the serious safety concerns raised by the whistleblower at this Medical Center. OMI provided a summary report solely addressing the status of the corrective actions. The whistleblower continued to observe violations of procedures that could impact patient safety, even after the agency assured OSC that corrective actions had been completed. Despite my request, the OMI declined to investigate the whistleblower's more recent, specific allegations. This refusal suggests that the VA is unwilling to correct substantiated deficiencies in the sterilization and processing divisions at this facility. It also reflects the lack of cooperation with whistleblower allegations evident in many other matters on which OSC has recently reported. Based on my review, I have determined that although the agency reports contain all the information required by statute, the findings do not appear reasonable given the whistleblower's ongoing concerns regarding compliance with safety procedures and the agency's decision to ignore these concerns.

As required by 5 U.S.C. § 1213(e)(3), I have sent unredacted copies of the agency reports and the whistleblower's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs.[6] I have also filed a redacted copy of the reports and the whistleblower's comments in our public file, which is now available online at www.osc.gov. This matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosures

[6] The VA provided OSC with a report containing employee names (enclosed), and a redacted report in which employees' names were removed. The VA cited Exemption 6 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the report produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the report in our public file. OSC objects to the VA's use of FOIA to remove these names because under FOIA, such withholding of information is discretionary, not mandatory, and therefore does not fit within the exceptions to disclosure under 5 U.S.C. § 1219(b), but has agreed to post the redacted version as an accommodation.