



U.S. OFFICE OF SPECIAL COUNSEL

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The Special Counsel

December 14, 2015

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

Re: OSC File No. DI-13-4272

Dear Mr. President:

Pursuant to my duties as Special Counsel, enclosed please find the Department of Veterans Affairs' (VA) reports based on disclosures of wrongdoing by employees at the Buffalo VA Medical Center (Buffalo VAMC), Buffalo, New York, reported to the Office of Special Counsel (OSC). OSC has reviewed the reports and, in accordance with 5 U.S.C. § 1213(e), provides the following summary of the allegations, the whistleblower's comments, and my findings.

The whistleblower, Lisa Magin, who consented to the release of her name, alleged that employees at the Buffalo VAMC engaged in conduct that may constitute a violation of law, rule, or regulation and a substantial and specific danger to public health. Specifically, she alleged that Sterile Processing Service (SPS) management failed to properly train employees, provide equipment cleaning instructions from manufacturers, or take sufficient action to correct or curtail the wrongdoing of SPS employees. Ms. Magin alleged that, because of these failures by management, SPS employees regularly failed to properly clean and sterilize reusable medical equipment (RME), did not adequately stock essential supplies on cardiac crash carts, and failed to comply with personal protective equipment (PPE) requirements.

**The investigation partially substantiated the whistleblower's allegations. It confirmed that SPS employees sometimes failed to comply with PPE requirements and occasionally failed to place sterilization indicators in peel pouches and sterilization locks on operating room (OR) trays, but found evidence that management held employees accountable for noncompliance. The investigation could not substantiate the allegation that employees do not properly clean dental hand pieces. Additionally, the agency determined that standard operating procedure (SOP) documents were available for each piece of equipment processed by SPS and that all full-time SPS employees had received training and certification as required by VA handbooks and directives. Further, the investigation revealed that employees were adequately stocking a sufficient number of cardiac crash carts for Buffalo VAMC use. I have determined that the reports contain all of the information required by statute and that the agency's findings appear reasonable.**

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OSC referred the allegations to then-Secretary of Veterans Affairs Eric K. Shinseki for investigation pursuant to 5 U.S.C. § 1213(c) and (d). Pursuant to Secretary Shinseki's request to the Under Secretary of Health, the Office of the Medical Inspector (OMI) conducted the investigation. Then-VA Chief of Staff Jose D. Riojas submitted OMI's report to OSC on behalf of the Secretary. The Office of General Counsel submitted a supplemental report at the request of OSC. Ms. Magin commented on the reports pursuant to 5 U.S.C. § 1213(e)(1). As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the agency reports and Ms. Magin's comments to you.<sup>1</sup>

### *The Disclosures*

Ms. Magin disclosed that SPS employees are not provided any formal training on how to clean RME. Rather, SPS employees are expected to learn how to clean the equipment on the job. Nevertheless, according to the whistleblower, manufacturer instructions on how to properly clean equipment are not available for employees to review. In addition, Ms. Magin reported that there are no SOPs for cleaning RME other than those related to cleaning scopes. Because of the failure to train or provide instructions, Ms. Magin alleges, SPS employees regularly failed to clean and sterilize RME, at risk to patients. To illustrate these allegations, Ms. Magin provided the information outlined below.

Ms. Magin disclosed that SPS employees clean the dental hand equipment solely with water, by wiping the equipment with a wet gauze pad, rather than by submerging it in a disinfectant enzyme cleaner and using cleaning brushes and syringes, as required. In addition, Ms. Magin stated that SPS employees frequently failed to place sterilization indicators in peel pouches and sterilization locks on OR trays and mislabeled the number of instruments in sets. When this is discovered, those items must be reprocessed. Ms. Magin also disclosed that SPS employees are not wearing the proper PPE. Specifically, she indicated that employees working on the decontamination process are not wearing head-to-toe protective equipment, including face shields, masks, booties, and the required blue jackets, and that employees working on the sterilization process fail to wear the required beard covers and long sleeve jackets to prevent hair from contaminating sterile instruments.

Finally, Ms. Magin disclosed that the Buffalo VAMC lacks adequately stocked cardiac crash carts. She explained that there was often just one cart available for the entire VAMC,

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<sup>1</sup>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).

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and the carts that were available were not stocked. Ms. Magin asserted that one cardiac crash cart is insufficient to ensure rapid emergency response for all patients.

*The Department of Veterans' Affairs Report*

The investigation concluded that SOP documents were available for each piece of equipment processed by SPS and that all full-time SPS employees had received training and certification as required by VA handbooks and directives. The relevant VHA directive and handbook require orientation and continued on-the-job training for all SPS employees in the initial 20 weeks of work in order to obtain Level 1 training, as well as a certification examination to obtain Level 2 training. OMI determined that the Buffalo VAMC has a SPS employee orientation checklist that provides guidance and documentation, with ongoing competency assessments for Level 1 training. All full-time SPS medical supply technicians had achieved Level 1 and 2 certifications.

In addition, OMI determined that the Buffalo VAMC underwent a substantive effort to convert all manufacturers' processing instructions to SOPs beginning in 2009. OMI reported that each piece of SPS equipment processed had a current SOP that was available to employees in hard copy on shelves in the clean preparation area of SPS and electronically on a Sharepoint site. All SPS employees also have access to oneSOURCE, the national online database for locating manufacturers' processing instructions. OMI also found that when SPS receives new equipment to process, SPS employees are trained by the manufacturer's representative. Further, the equipment is not released for use until the manufacturer's instructions are converted to a SOP and placed on the Sharepoint site.

The investigation also concluded that there were a sufficient number of adequately stocked cardiac crash carts. OMI determined that, pursuant to Buffalo VAMC policy, Logistics employees, with the assistance of Pharmacy and SPS employees, maintained 30 cardiac arrest carts. Twenty-five of the carts are deployed throughout the facility at locations designated by the policy. Five backup carts are available as replacements and are kept either in Logistics during processing or in the Logistics hallway once fully stocked and available for use. There is also a crash cart log board outside of the SPS-Logistics area that specifies the location and status of each crash cart.

OMI also investigated Ms. Magin's specific examples of failure to properly clean and sterilize RME and failure to properly wear PPE. The investigation could not substantiate the allegation that SPS employees did not properly clean dental hand pieces before sterilization. Although OMI did not observe SPS employees cleaning dental equipment during the site visit, OMI reviewed the SOPs for several types of dental equipment and was provided a demonstration by SPS employees that complied with the SOP. The investigation substantiated the allegations that SPS employees failed to comply with the standards for wearing PPE, failed to place sterilization indicators in peel pouches and sterilization locks on OR trays, and have mislabeled or miscounted sterile instruments in trays. Nevertheless, OMI determined VAMC leadership previously identified these issues and took action to correct and control the issues through additional training and implementing progressive discipline for

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employees who are noncompliant. OMI reviewed close call reports, which did not reveal any instance in which improperly processed instruments were used on a patient during any surgical procedure. OMI also reviewed the postoperative sepsis rate for the facility, which declined during the relevant time period and was below the VA's national average.

OMI made several recommendations to the facility, which Buffalo VAMC have implemented. First, OMI recommended that the facility support the ongoing relationship and effective communication between Dental Office staff and SPS employees. In response, the facility holds monthly meetings. Second, OMI recommended that Buffalo VAMC continue training on the importance of correct PPE use and develop an appropriate approach to counter employee noncompliance. The Buffalo VAMC now requires each employee complete an annual competency on PPE and has instituted progressive discipline for employees who are noncompliant with these requirements. Third, OMI recommended the SPS practice of two-person sterile tray inspections and two-person signature sign-offs on product inspections continue. The Buffalo VAMC re-educated staff on this policy and practice in 2014. Finally, OMI recommended that the facility develop a systematic approach to analyzing SPS close call quality improvement data. The Buffalo VAMC developed and implemented a tool to track noncompliance and corrective actions, with close calls reported monthly to the Reuseable Medical Equipment and Infection Prevention Committees, and SPS supervisors providing additional training, as needed.

#### *The Whistleblower's Comments*

Ms. Magin asserts that OMI's investigation was flawed and her allegations were not properly investigated. She asserts that SOPs were not available to SPS employees and training was not provided. She commented that the OMI did not interview a sufficient number of SPS employees, relied heavily on what they were told by Buffalo VAMC management, and did not review all of the evidence she provided. Finally, Ms. Magin expressed concern that OMI overlooked 44 close call reports between 2011 and 2013 that resulted in a delay to patient care. She maintains that the training and progressive discipline are not effective in curtailing employee wrongdoing in SPS.

#### *The Special Counsel's Findings*

I have reviewed the original disclosure, the agency reports, and the whistleblower's comments. I applaud Ms. Magin's commitment to patients and understand her concerns regarding both the scope of OMI's investigation and accountability at Buffalo VAMC. I also appreciate Ms. Magin's valuable on-the-ground perspective and that her view of the problems and implemented corrective measures differs from that of OMI investigators. Nevertheless, I am satisfied with the agency's investigation and the corrective measures OMI recommended. Thus, I have determined that the reports contain all of the information required by statute and find the agency's conclusions reasonable.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the unredacted agency reports and the whistleblower's comments to the Chairmen and Ranking Members of the

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Senate and House Committees on Veterans' Affairs. I have also filed copies of the redacted agency reports and whistleblower's comments in OSC's public file, which is available online at [www.osc.gov](http://www.osc.gov).<sup>2</sup> This matter is now closed.

Respectfully,



Carolyn N. Lerner

Enclosures

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<sup>2</sup>The VA provided OSC with reports containing employee names (enclosed), and redacted reports in which employees' names were removed. The VA has 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 reports produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the reports 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 of the reports as an accommodation.