September 29, 2023

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

Re: OSC File Nos. DI-21-000643 and DI-21-000651

Dear Mr. President:

I am forwarding to you reports transmitted to the Office of Special Counsel (OSC) by the Secretary of Veterans Affairs (VA), in response to the Special Counsel’s referral of disclosures of wrongdoing at the Veterans Healthcare System of the Ozarks (VHSO), Gene Taylor Community Based Outpatient Clinic (CBOC), Springfield, Missouri. The whistleblowers, [...], who consented to the release of their names, are employees in the CBOC’s Sterile Processing Service (SPS). I have reviewed the disclosure, agency reports, and whistleblower comments and, in accordance with 5 U.S.C. § 1213(e), have determined that the reports contain the information required by statute and the findings appear reasonable. As summarized below, the agency substantiated some of the allegations.

The Whistleblowers’ Allegations

[...], disclosed that VHSO and CBOC management violated Occupational Safety and Health Administration (OSHA) regulations and Veterans Health Administration (VHA) directives regarding environmental controls, risk assessments, and safety thereby placing SPS patients and staff at risk. They alleged the following: the SPS decontamination and reprocessing rooms did not consistently meet temperature, humidity, and air turnover requirements; the SPS did not have an anteroom where staff could put on and remove personal protective equipment (PPE), which created a contamination risk; improper risk assessments eliminated the need for an emergency shower in the SPS; and the SPS reprocessing room was improperly labeled as a decontamination room so that the SPS staff was required to wear PPE in that room.

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1 OSC referred the allegations to Secretary of Veterans Affairs Denis McDonough for investigation pursuant to 5 U.S.C. § 1213(c) and (d). The Office of the Medical Inspector investigated the allegations and Secretary McDonough reviewed and signed the agency report.
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The Reports’ Conclusions Regarding the Whistleblowers’ Allegations

The reports substantiated that the SPS decontamination and reprocessing rooms did not consistently meet temperature, humidity, and air turnover requirements. The reports also concluded that air handler unit #8, which covers the endoscopy suite and the SPS area, did not have the proper air filter. As a result, the maintenance staff ensured that the property’s Building Automation System (BAS), which controls the environmental conditions of the endoscopy suite and SPS area, was working correctly and verified the BAS environmental readings with an infrared thermometer. The maintenance staff also confirmed that the CheckPoint thermostats were operating correctly and not placed near equipment or conditions that would influence readings. The CBOC’s engineering service updated the thermostats’ preventive maintenance schedule to include changing batteries, confirmed that the CheckPoint system’s automated monitoring capabilities included real time temperature and humidity readings every 15 minutes, and ensured that the system sends notices to staff when a thermostat is not working so that the CBOC’s engineering service can repair the device as needed. Also, the property manager installed the required air filter for air handler unit #8.

Although the investigation substantiated that the SPS area did not have an anteroom, the reports concluded an anteroom was not required because the SPS area was designed as part of the endoscopy suite and pursuant to VA Office of Construction & Facilities Management Design Guide, Digestive Diseases – Endoscopy Service, does not require an anteroom. The reports did not substantiate that management conducted improper risk assessments of the SPS’s need for an eyewash station but not an emergency shower. Both assessments reviewed how the SPS staff handled the chemical in question, Rapicide PA, and determined there was minimal risk of saturating the skin or clothing, which obviated the need for an emergency shower under VHA directives. Further, the reports did not substantiate that management improperly relabeled the SPS reprocessing room as a decontamination room because management had already determined—in response to an OSHA complaint—that the reprocessing room functioned as a decontamination area and changed the PPE standards to align with VHA requirements.

The reports also contained findings and conclusions related to the SPS including its workflow and construction. VHA directives require a facility Chief of SPS, the National Program Office for Sterile Processing (NPOSP), and the VA Office of Construction and Facilities Management (VA CFM) to approve a facility’s SPS design configuration; the Chief of SPS consults with NPOSP and VA CFM at various stages of the SPS construction or renovation design and planning process. The SPS workflow pattern must be designed to contain contaminants and minimize employee exposure to pathogens, and hygiene practices must be strictly kept to prevent cross-contamination. Further, when endoscopes are clean, reprocessed, and dry, they

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2 The reports noted that SPS employees did not pour Rapicide PA into the Automated Endoscope Reprocessor (AER)—the sealed, interlocked cleaning and disinfecting system that reprocesses endoscopes—but exchanged an empty Rapicide PA container for a full one on the floor at the base of the machine.

3 Rapicide PA is a high-level disinfectant and corrosive chemical that can cause eye and skin damage.
must be stored in a clean, closed, vented area outside of the decontamination and reprocessing rooms.

The reports concluded that the SPS workflow in the decontamination and reprocessing rooms presented a high-risk of cross-contamination due to room configuration, equipment location, and the non-linear workflow of employee movement. The reports concluded that the SPS appropriately used a cabinet—the Medivators EndoDry Storage and Drying System—to store clean endoscopes but determined that keeping the cabinet in the reprocessing room risked cross-contamination. The reports found that these issues may have resulted in contaminated endoscopes being used in patient procedures. Additionally, the reports determined that during the CBOC’s construction, VHOSO failed to submit the SPS room design plans to NPOSP for review and approval at the required development stages pursuant to VHA directives. Even though an NPOSP review of the design plans at the 50% complete stage identified several design issues that needed correction, the CBOC failed to address them before completing construction, and as a result, the CBOC failed to implement all VHA requirements in the SPS rooms.

Consequently, the CBOC suspended endoscopy procedures and SPS operations while these areas undergo a redesign and renovation to address the cross-contamination risks. The NPOSP, the Office of Healthcare Environment and Facilities Programs, Veterans Integrated Service Network (VISN) 16, and VHOSO and CBOC staff developed the renovation plans, which address workflow and applicable VA requirements. The renovation statement of work includes a full test and balance of the environmental conditions and air flow in the endoscopy suite which will occur before procedures resume. Also, the CBOC’s industrial hygienist, safety staff, and management will receive training on performing risk assessments in alignment with VHA directives. The SPS staff will receive refresher training on PPE and infection prevention and the Quality, Safety and Value Service will perform random tracers/observations at the SPS to ensure compliance, any non-conformities will be reported to the Chief of SPS for remediation. Finally, VHOSO quality management clinically reviewed all endoscopy procedures performed while the suite was operational and followed all patients for 30-days post-procedure. None of the procedures resulted in any complications, infections, or other negative impacts to patients.

The Whistleblowers’ Comments

[Redacted] objected to how the investigation was conducted and disputed the report’s conclusions regarding the unsubstantiated allegations. They also critiqued the reports as inconsistent and negatively biased towards them. [Redacted] further criticized their treatment by management since the allegations were referred, alleging it was retaliatory. I thank the whistleblowers for bringing these serious allegations to OSC’s attention. Their efforts resulted in significant corrective action that will improve the operation of the SPS at the facility. As required by 5 U.S.C. § 1213(e)(3), I have sent copies of this letter, the agency reports, and whistleblower comments to the Chairmen and Ranking Members of the Senate
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and House Committees on Veterans’ Affairs. I have also filed redacted copies of these documents and the redacted referral letter in our public file, which is available online at www.osc.gov. This matter is now closed.

Respectfully,

[Signature]

Henry J. Kerner  
*Special Counsel*

Enclosures