DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

OCT 26 2016

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

RE: OSC File No. DI-15-2103

Dear Ms. Lerner:

The enclosed Department of Veterans Affairs (VA) Supplemental Report: New Mexico VA Health Care System, Albuquerque, New Mexico (the Medical Center), responds to your email of September 21, 2016, posing two follow-up questions regarding the Sterile Processing Service (SPS) at the Medical Center. The report details the process for bedside cleaning of endoscopes to answer the first question, and the status of SPS employees inquired about to answer the second. VA makes no further recommendations to the Medical Center.

Thank you for the opportunity to respond.

Sincerely,

David J. Shulkin, M.D.

Enclosure

Department of Veterans Affairs
Supplemental Report to the
Office of Special Counsel
New Mexico Veterans Affairs Health Care System
Albuquerque, New Mexico
OSC File No. DI-15-2103

October 18, 2016
TRIM 2016-D-2301

Background

The Under Secretary for Health requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the New Mexico VA Health Care System (the Medical Center), in Albuquerque, New Mexico. Alfred Smith, the whistleblower, who consented to the release of his name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on August 3−6, 2015, and submitted its report to OSC on January 5, 2016. OSC posed seven questions for details on that report, to which VA responded with a supplemental report of August 10, 2016. The supplemental report elicited two further questions from OSC on September 21, 2016. This second supplemental report answers those questions.

Specific Allegations of the Whistleblower

1. Surgical technicians habitually fail to conduct point-of-use cleaning of reusable medical equipment (RME) and often comingle used RME;

2. Sterile Processing Service (SPS) employees regularly fail to use tracking software to account for individual trays of RME and do not follow SPS protocols;

3. SPS employees improperly alter cleaning test data for endoscopic and dental equipment to show negative test results; and

4. SPS decontamination and sterile processing areas are not cleaned on a regular basis. Based on its investigation, VA made eight recommendations for the Medical Center.

Pursuant to 5 U.S.C. § 1213(d), VA submitted its investigative report to OSC on January 5, 2016. To make the requisite determinations under section 1213(e), OSC requested additional information on September 21, 2016. This supplemental report serves as VA's response to the September 21 request. VA's responses follow OSC's questions below.

OSC Question 1: The whistleblower raised a specific concern with regard to the report's description of carts with evidence of dried instruments and pooling liquid at the bottom. The report explained that this is evidence of a cart with instruments that were sprayed with Prepzyme but were not immediately processed but were instead left for extended periods, resulting in drying. The whistleblower's specific concern was the effect of this cycle of spraying and drying on endoscopes. The whistleblower noted that endoscopes may contain bio-burden on and inside the endoscope's flexible channels, which are difficult to reach. If bio-burden is left to dry and becomes encrusted inside the channels, it could significantly increase the risk of infection transmission. Was there any evidence suggesting that Prepzyme was or was not used inside the channels of the endoscope, or was the review limited to the use of Prepzyme on surfaces only? Does VHA policy or manufacturer instructions recommend or require spraying Prepzyme inside the channels in addition to the surface of the endoscopes?

VA response: Unlike surgical instruments, precleaning of endoscopes occurs at the bedside before sending them for high-level disinfection in the processing area. OMI reviewed Nursing-Operating Room Standard Operating Procedure (SOP), Pre-cleaning of Olympus GIF/CF/PCF 190 series endoscopes, which details the bedside pre-cleaning for these instruments using the manufacturer's instructions for use and instrument-specific cleaning equipment. The procedure specifies setting the flexibility adjustment on the instrument to maximum, and the process for wiping the insertion end of the instrument with Endozyme detergent solution. Next, the technician uses a provided device to aspirate the Endozyme solution through the lumen from the distal end of the instrument for a minimum of 10 seconds, and follows up with the aspiration of air via the same route for a minimum 10 seconds to remove any residual detergent solution. Both the air/water channel and auxiliary water channel are flushed with water in accordance with the manufacturer's instruction. This occurs prior to delivery to the decontamination area in SPS. The intent of this procedure is to eliminate as much of the bioburden as possible so that it will not dry on the equipment. The intent of the Endozyme detergent solution, like the Prepzyme solution used on other instruments, is to prevent soil from drying on the instruments, thus eliminating the concern for excessive cycling of wet and dry phases. The Veterans Health Administration follows all manufacturers' instructions for use in addition to the SOP outlined above.

OSC Question 2: The report indicates that, as of March 2016, all of the VA employees involved in the purchase of the Censitrac system had left the VA. The whistleblower, however, indicated that the purchase decision was an SPS joint management consensus involving past and present SPS management, and several of the individuals involved are still employed by the VA. The employees are: Stephanie Bobelieu-Boone, who is still employed at the RGM VAMC as assistant chief and Robert Coffey, who is still employed as 1st shift supervisor. Further, the whistleblower indicated that former employee Susan Heyward was still employed at the facility in March 2016. Can you please provide a review of

the status and involvement of these employees and an update on the agency's determination not to seek any disciplinary action in light of any new findings?

VA response: The Medical Center conducted a fact finding in March 2016, and determined the former SPS Assistant Chief was the designated Censitrac Project Manager. He resigned in December 2012. The only other employee directly involved with the procurement of the Censitrac System during the VA site visit was Susan Heyward, who left employment with VA in April 2016. Ms. Heyward indicated that she was responsible for pushing the Censitrac System, as she felt this would improve operations in SPS. The Medical Center had detailed Ms. Heyward out of her role as SPS Chief prior to the VA visit. The other two employees listed were not responsible for the decision to purchase. As members of the management team, they knew of the Censitrac purchase, and knew the implementation start date, but were not directly involved with any procurement discussions.