DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

April 19, 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-15-5181

Dear Ms. Lerner:

I am responding to your request for supplemental information related the Veterans Health Administration's (VHA) December 7, 2015, report on the Southern Arizona Department of Veterans Affairs Medical Center, in Tucson, Arizona (hereafter, the Medical Center). You requested an update on the actions taken by the Medical Center and VHA in response to the recommendations in the original report.

The enclosed supplemental report furnishes the updates and makes no additional recommendations to the Medical Center.

If you have any other questions, I would be pleased to address them. Thank you for the opportunity to respond.

Sincerely,

David J. Shulkin, M.D.

Enclosure

Department of Veterans Affairs (VA)
Supplemental Report to the
Office of Special Counsel (OSC)
OSC File Number DI-15-5181

Southern Arizona VA Health Care System
Tucson, Arizona

April 13, 2016
TRIM 2016-D-1027

Background

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a team to investigate allegations lodged with OSC concerning the Southern Arizona VA Health Care System, (hereafter, the Medical Center) located in Tucson, Arizona. Lena Denise Cruz alleged that employees in Sterile Processing Service (SPS) consistently fail to follow proper procedures in decontaminating, cleaning, sterilizing, packaging, storing, and distributing reusable medical equipment (RME), and 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 visited the Medical Center on August 31–September 4, 2015.

Allegations

1. Sterile Processing staff does not perform decontamination, cleaning, sterilization, packaging, storing, and distribution of medical and surgical device processes in accordance with competencies established by device manufacturers and VA procedures, thus increasing the possibility of contamination.

2. Sterile Processing managers emphasize speed over compliance with the competencies.

3. Sterile Processing is grossly understaffed and does not have the manpower to meet the decontamination, cleaning, sterilization, and packaging competencies.

4. Sterile Processing managers falsify official government documents regarding education and training of medical supply technicians in order to satisfy VA record keeping requirements and pass periodic inspections.

Based on its investigation, the VA report, endorsed by the USH and signed by the VA Chief of Staff, made six recommendations for the Medical Center and two for the Veterans Health Administration (VHA).

On April 5, 2016, OSC requested that VA detail in a supplementary report the progress made on the February 18, 2016, Action Plan developed in response to the VA report recommendations.

Recommendations to the Medical Center:

Recommendation 1: Develop a protocol for the operating room (OR) to immediately notify SPS when an RME is acquired from outside vendors, to facilitate a smoother and less urgent response for SPS processing.

Resolution: The Medical Center developed a standard operating procedure (SOP), "SOP 20, Management of Borrowed Instrumentation including Non-Biological Implants," and published it on March 21, 2016.
Action Completed.

Recommendation 2: Provide training/tools on effective communication for SPS staff.

Resolution: The Medical Center initiated eight separate training actions to address improving effective communication for SPS staff. Training is on schedule to be completed by June 27, 2016.
Action Ongoing.

Recommendation 3: Consult with National Center for Organizational Development (NCOD) or an outside consultant to implement team building for SPS staff on all tours of duty.

Resolution: NCOD conducted two consultations with the Medical Center on SPS team building in February and March 2016; the Medical Center is in the process of implementing the NCOD recommendations.
Action Ongoing.

Recommendation 4: Fill medical supply technician vacancies as soon as possible, and consider the use of temporary contract staff in SPS while new staff is on-boarded and trained.

Resolution: The Medical Center filled the vacant positions in November 2015; by February 2016, all new staff members had completed orientation and were working their tours of duty. The Medical Center continues to explore a variety of ways to respond to future staff shortages. This process will be completed by July 2016.
Action Ongoing.

Recommendation 5: Continue to monitor the SPS quality indicators (e.g., OR incident reports, Corrective Action/Prevention Action (CAPA) forms, Surgery Care Line Quality Improvement (SCL QI) forms, etc.) for trends and continue to take appropriate actions in response.

Resolution: The Medical Center has monitored its SPS quality indicators for over 2 years, and has implemented additional actions to improve information flow between the OR and SPS regarding quality indicators. The Medical Center added SPS quality indicators and OR incident reports as standard agenda topics in the monthly RME committee meeting in August 2015 (SPS quality indicators), and February 2016 (OR incident reports).
Action Ongoing.

Recommendation 6: At the direction of the investigation team the Medical Center convened an Administrative Investigation to reconcile the contradictory testimony about a supervisor completing Talent Management System (TMS) training on behalf of an employee. This investigation is underway; if evidence is found that substantiates the allegation, take appropriate administrative and disciplinary action.

Resolution: The Administrative Investigation closed December 2015. An additional fact-finding completed by the facility subsequent to this investigation proposed disciplinary actions in March 2016. VA is awaiting the final action on proposed discipline after employees' due process time. Expected completion of this process is May 2016.
Action Ongoing.

Recommendations to VHA:

Recommendation 1: Review the requirements that mandate writing SOPs on each individual piece of RME, to determine how to make the competency assessment process more efficient.

Resolution: VHA is reviewing the requirements that mandate writing SOPs on each individual piece of RME and evaluating its response to this recommendation.
Action Ongoing.

Recommendation 2: As recommended in OSC File Number DI-15-2103, VHA should publish a handbook to address the specific SPS portions of VA Directive and Handbook 7176, *Supply, Processing, and Distribution*, as soon as possible.

Resolution: VHA Directive 1116, *Sterile Processing Services*, was published March 23, 2016.
Action Completed.