DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

February 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-15-0563

Dear Ms. Lerner:

I am responding to your request for supplemental information related to our July 8, 2015, report on the Washington DC Veterans Affairs Medical Center, Washington, DC (hereafter, the Medical Center). Your request poses two questions covering the Medical Center's and the Veterans Health Administration's actions taken in response to the respective recommendations made to them in the original July 2015 report.

The enclosed supplemental report replies to both questions 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 Supplemental Report
to the
Office of Special Counsel
OSC File Number DI-15-0563

Washington, DC Veterans Affairs Medical Center
Washington, DC

February 19, 2016

TRIM 2016-D-340

Reponses to OSC's Request for a Supplemental Report on the Recommendations in VA's Report Regarding OSC Report File No. DI-15-0563.

OSC Request for Supplemental Report: The agency's report in the matter above (DC VAMC – leaking endoscopes), dated July 8, 2015, made two recommendations as a result of the investigation. The first recommended that the facility seek assistance from the National Program Office for Sterile Processing. The second recommended that VHA convene a Clinical Review Board (CRB) to assess the risk of possible infection to patients as a result of the failure to leak test endoscopes at the DC VAMC. We are requesting an e-mail update on the status of these recommendations, including any findings of the CRB or actions taken as a result of the CRB.

1. **Recommendation to the Medical Center:** Request an assistance visit from the National Program Office for Sterile Processing (NOSP) for guidance on consolidating sterile processing operation.

   The NOSP conducted a Site Assistance Visit on April 6−8, 2015. As a result, plans to consolidate processes were developed and implemented. All implemented process changes, staff compliance with training requirements, and process outcomes continue to be tracked by NOSP.

   Additionally, a follow-up visit was conducted September 22, 2015. The NOSP is the lead for following up on any actions undertaken by the Medical Center.

2. **Recommendation to VHA:** Convene the Clinical Review Board to assess the risk of possible infectious exposure to patients due to the lack of leak testing prior to 2008, and based on its findings, recommend to the I/USH whether a large-scale disclosure is warranted.

   The Clinical Episode Response Team (CERT) met on August 31, 2015, to discuss the report recommendation. (The CERT committee is comprised of representatives from the Offices of the Deputy Under Secretary for Health for Operations and Management; the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; General Counsel; Nursing; Ethics; Public Health;

Risk Management; and other offices and field-based subject matter experts to determine whether an adverse event involves negligible or clinically significant risk of harm, which may warrant large-scale disclosure).

Based on the facts presented, the CERT committee assessed the probability of patient harm and agreed that in the matter of leak testing prior to 2008; patient harm was negligible and does not warrant large-scale disclosure or CRB assessment. The Assistant Deputy Under Secretary for Health for Clinical Operations reviewed the committee's findings, and concurred in a memorandum signed October 22, 2015, that convening the CRB was not warranted.