DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

DEC 11 2015

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 on the Washington Department of Veterans Affairs (VA) Hospital, (the Medical Center) Washington, DC, in response to the 4 main follow-up questions and 10 supplementary points posed in your request for further information of November 9, 2015.

This supplemental report answers the three main questions on leak testing, visual inspections, and disinfectant in use. The fourth main question on various aspects of cleaning and disinfecting in general is dealt with in responses to each of its 10 specific points. This report makes no supplemental 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, District of Columbia

December 10, 2015

TRIM 2015-D-6834

Reponses to Office of Special Counsel (OSC) follow-up questions on the Washington DC Report, OSC File No. DI-15-0563

OSC Question 1: On page ii of the report, the agency asserts that the endoscopes at issue were cleaned and disinfected in accordance with manufacturers' guidelines prior to 2008. However, the whistleblower asserts that leak testing is considered part of the cleaning process, and manufacturers' guidelines all require leak testing. Please reconcile these two assertions.

VA Response: Leak testing is a preventative measure to ensure major damage does not occur to an endoscope. Any fluid ingress into the optical bundle of a fiberscope or video scope will cause major damage, resulting in high-cost repairs.

OSC Question 2: We are perplexed by the assertion that holes or damage would be seen by a provider with the naked eye before being used on a patient. The whistleblower asserts that not all holes or damage are initially visible to the naked eye, but can still be hazardous to patients. This seems supported by the fact that the whistleblower identified several endoscopes in 2008 that had leaks in need of repair, but these leaks were only identified *once a leak tester was purchased and used*. In other words, prior to the use of the leak tester, no provider had identified that the endoscopes were leaking. This is noted in the agency's report on page 8. Please explain the agency's finding in light of this information.

VA Response: As noted on page 12 of the report, the Chief of the ENT Service began working in the clinic in 2007 and became the Service Chief in 2008. She indicated that the purpose of leak testing is to test the seal of the scope, and that if the scope failed a leak test, the clinic would take it out of service and send it out to the vendor for repair. She also stated that during her tenure in the clinic, many endoscopes had been taken out of service for various issues and that some had been retired. Prior to insertion of the endoscope into a patient, she routinely inspects each instrument as follows:

A. The scope control section is checked for excessive scratching.
B. The scope boot and insertion tube are checked for dents, bulges, swelling, peeling, or other irregularities.

C. The entire length of the insertion tube is checked for protrusions and any other irregularities by running the fingertips down the length of the tube.
D. The bending section's covering is checked for sagging, swelling, cuts, holes or other irregularities.

With a thorough visual inspection of the endoscope, observed abnormalities, (which may include a hole or damage), can be detected and scopes removed from service.

Also in 2008, CDC changed its guidelines for disinfection and sterilization in health care facilities; it was not until 2009 that the Academy of Otolaryngology adopted these CDC guidelines, as noted in the report.

OSC Question 2a: In addition, leaks may develop over a long period of time, as may visible damage to the scope or the pictures produced by the scope. During that period, the scope may be used on many patients before the leak or damage is detected. Please address this concern in light of the agency's review of the potential danger to public health and safety as a result of the failure to leak test.

VA Response: During reprocessing with the use of High Level Disinfectant, cleaning and disinfecting fluids have access to the same areas beyond the leak as do biological materials, thereby killing bacteria and viruses.[1]

OSC Question 3: The whistleblower asserts that Cidex OPA, the disinfectant used to clean the endoscopes, is well-known to be potentially ineffective in the presence of biomaterial. In addition, because some holes may be positional, and not constant, the Cidex OPA may not travel the same path as any biomaterial through the scopes. Please address these concerns in the context of the report finding that the cleaning process would inactivate biohazardous materials (page iii).

VA Response: Cidex has been on the market for more than 25 years, and Cidex OPA for 12. These products are still considered to be the best available for High Level Disinfection.[2]

OSC Question 4: The whistleblower further notes that the report incorrectly states that the whistleblower told investigators that "before 2008 the instruments had been cleaned and disinfected according to the prevailing standards at the time." The whistleblower reports that he informed investigators during his interview that most steps in the cleaning and disinfecting process were deficient prior to 2007, going back to at least 1995. The whistleblower followed up his interview with an e-mail to Trini Jeanice, dated March 19, 2015, containing a ten-point list of deficiencies, copied below for your reference. Please reconcile these statements and assess them in light of the agency's

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[1] EndoNurse: The Authority for the Continuing advancement of Endoscopic Nursing. Leak Testing, March 30, 2007.
[2] FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2015 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm.

OSC Question 4a: Before 2007 lack of timers for timing of Cidex OPA soak times.

VA Response: Timers are a convenience; any clock or watch may be used for soaking an endoscope in Cidex OPA.

OSC Question 4b: Before 2007 lack of a written SOP (standard operating procedure).

VA Response: VA Handbook 7176 of August 16, 2002 states, "Before processing any scope, the technician should consult all manufacturers' instructions."[3] VHA Directive 2009-004 of February 9, 2009, provided guidelines; which required written SOP detailing all steps required for a process. Prior to the Directive, technicians used the manufactures' instructions as SOPs were not a requirement.

OSC Question 4c: Before 2007, lack of a wall clock for timing of cidex test trip quality checks.

VA Response: VA Handbook 7176, dated August 16, 2002, states, "Before processing any scope, the technician should consult all manufacturers' instructions." VA was told by the whistleblower that he used his watch as no wall clock was present.

OSC Question 4d: Before 2008, use of MAJ-210 biopsy port covers on the PEF Type V scope.

VA Response: These scopes are non-channeled flexible endoscopes. The MAJ-210 water-resistant cap is included in the accessories provided with the sale of the ultrasonic endoscope. The MAJ-210 may also be purchased as a disposable, single-use item. The cap allows the endoscope to be safely immersed in solution. The site visit team was neither shown nor sent documents indicating that the PEF Type V scope was sent each time to the vendor after use due to processing failure based on no MAJ-210 cap.

OSC Question 4e: Before 2008, lack of suction equipment.

VA Response: In lieu of power suction, technicians use large syringes to suction/aspirate a channeled scope ensuring bioburden was removed from the walls of a channeled scope. This is certainly a viable option for an urgent/emergent facility contingency plan. Following the manual cleaning process, endoscopes are high level disinfected and or sterilized according to manufacture guidelines. According to Washington DC VAMC reports, there were no infections linked to the cleaning and processing of scopes during the period in question.

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[3] VA Handbook 7176 was rescinded on March 13, 2012 http://www.va.gov/vapubs/viewPublication.asp?Pub_ID=609&FType=2.

OSC Question 4f: Before 2008, lack of leak testing equipment.

VA Response: According to Washington DC VAMC reports, no infections were linked to the cleaning and processing of non-channeled endoscopes during the period in question.

OSC Question 4g: Before 2008, lack of power outlets to support suction or leak testing.

VA Response: The endoscopes being used were nonchanneled, and therefore, did not require suctioning. However, if a channeled scope was cleaned in the area in lieu of power suction, technicians would use large syringes to suction/aspirate the channel, ensuring bioburden is removed from the walls of a channeled scope.[4]

OSC Question 4h: Before 2008, lack of temperature testing for Cidex OPA.

VA Response: Part of this period Cidex testing strips were recalled by the manufacturer due to "performance failure complaints, moisture ingress into the bottles was causing failure and variability in results."[5]

OSC Question 4i: Lack of bioburden testing for the PEF Type V scope.

VA Response: In June 2006, according the Olympus America Web site, under "infection control," bioburden testing was not defined as a requirement.[6] In August 2014, that Web site stated that endoscope reprocessing policies should include a procedure for monitoring the quality of endoscope reprocessing on a regular basis—whether per procedure, daily, weekly or even by random sampling.[7]

OSC Question 4j: Before 2008, lack of a MAJ-1219 cleaning adapter for the PEF Type V scope.

VA Response: According to Washington DC VAMC reports, there had been no infections linked to the cleaning and processing of nonchanneled endoscopes during the period in question.

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[4] The testimony of John D. Daigh Jr., MD, CPA, Assistant Inspector General, before the Subcommittee on Oversight and Investigations committee on Veteran Affairs, in June 2009, identified no patient safety alerts from February 10, 2003 to December 22, 2008 based on leak testing of non-channeled endoscopes. (http://www.va.gov/oig/pubs/statements/VAOIG-statement-20090616-daigh.pdf.

[5] http://www.fda.gov/Safety/Recalls/EnforcementReports/2004/ucm120316.htm.

[6] http://medical.olympusamerica.com/sites/default/files/pdf/mic0605p74.pdf.

[7] http://medical.olympusamerica.com/sites/default/files/pdf/EndoNurseReprocessing.pdf.