DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

July 8, 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 letter regarding allegations made by a whistleblower at the Washington DC Department of Veterans Affairs (VA) Medical Center (hereafter, the Medical Center), Washington, District of Columbia. The whistleblower alleged that Medical Center employees may have engaged in conduct that may constitute violations of laws, rules or regulations, gross mismanagement, and a substantial and specific danger to public health. Specifically, the whistleblower alleged that the Medical Center failed to leak test endoscopes after use and failed to inform patients of possible exposure to unsafe endoscopes. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

The Secretary asked that the Interim Under Secretary for Health refer the whistleblower's allegations to the Office of the Medical Inspector who assembled and led a VA team to conduct an investigation. VA could not substantiate the first allegation and did not substantiate the second, but made one recommendation to the Medical Center and one to the Veterans Health Administration (VHA). Findings from the investigation are contained in the enclosed report, which I am submitting for your review. I have reviewed these findings and agree with the recommendations in the report. We will send your office follow-up information describing actions that have been taken by the Medical Center and the VHA to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,

Robert L. Nabors II
Chief of Staff

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Report to the
Office of Special Counsel
OSC File Number DI-15-0563

Department of Veterans Affairs
Washington DC Veterans Affairs Medical Center
Washington, District of Columbia

Report Date: June 11, 2015

TRIM 2015-D-1400

Executive Summary

The Interim Under Secretary for Health (I/USH) 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 Washington DC VA Medical Center, (hereafter, the Medical Center) located in Washington, DC. John C. Leahy, RN (hereafter, the whistleblower), who consented to the release of his name, alleged that employees may have engaged in conduct that may constitute violations of laws, rules or regulations, gross mismanagement, and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on March16–19, 2015.

Specific Allegations of the Whistleblower

1. The facility's failure to leak test flexible endoscopes in the DC VAMC Ear, Nose, and Throat (ENT) Clinic potentially placed thousands of patients at risk of exposure to infection; and

2. The facility failed to notify affected patients upon learning of the potential exposure.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions

- VA **was not able to substantiate** that the Medical Center's failure to leak test flexible endoscopes in the ENT Clinic prior to August 2008 potentially placed thousands of patients at risk of exposure to infection.

- Although leak testing was not instituted until August 2008, VA found that flexible fiberoptic nasopharyngoscopes have been properly cleaned and disinfected after each patient use in accordance with established guidelines and the manufacturer's recommendations, both before and since that time.

- If a leak had developed in the external sheath of a flexible fiberoptic nasopharyngoscope before leak testing was instituted, but the instrument then underwent sterile processing, the next user would most likely have recognized evidence of damage to internal structures such as poor image quality or other malfunction. Even in the absence of such evidence, the high-level disinfectant fluids

used in sterile processing would follow the same path via the leak site as any potentially biohazardous materials, and would inactivate them.

- VA **did not substantiate** the allegation the facility failed to notify affected patients upon learning of the potential exposure. Other than one cautionary email sent by the whistleblower to ENT Clinic managers on August 18, 2008, there is no record of further communication regarding these concerns, nor is there evidence that an adverse event occurred, such as a higher than expected number of deleterious health outcomes among ENT Clinic patients due to exposure to infectious agents.

- Although there is no clear evidence of a substantial and specific threat to public health and safety resulting from the Medical Center's failure to perform leak testing prior to 2008, VHA should employ its existing methods for assessing the probability of patient harm and whether patient disclosure is ethically warranted.

Recommendation to the Medical Center

1. Request an assistance visit from the National Program Office for Sterile Processing for guidance on consolidating sterile processing operations.

Recommendation to VHA

2. 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.

Summary Statement

VA has developed this report in consultation with other Veterans Health Administration (VHA) and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the Office of General Counsel (OGC) has provided a legal review, and the Office of Accountability Review (OAR) has examined the issues from a Human Resources (HR) perspective to establish accountability, when appropriate, for improper personnel practices. VA found no violations of law, rule or regulation.

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I. Introduction

The I/USH requested that OMI assemble and lead a VA team to investigate allegations lodged with OSC concerning the Medical Center. The whistleblower, who consented to the release of his name, alleged that the facility's failure to leak test flexible endoscopes in the ENT Clinic potentially placed thousands of patients at risk of exposure to infection; and that the facility failed to notify affected patients upon learning of the potential exposure. The VA team conducted a site visit to the Medical Center on March 16–19, 2015.

II. Facility Profile

The Medical Center consists of the main hospital and five community-based outpatient clinics. It is a tertiary care, complexity level 1B hospital, providing comprehensive primary and specialty care in medicine, surgery, neurology and psychiatry. The Medical Center has 175 acute care beds, 30 Psychosocial Residential Rehabilitation Treatment (PRRTP) beds, an adjacent 120-bed Community Living Center (CLC), a 20-suite Fisher House and full service Women's Health Clinic equipped with digital mammography and gynecological care. The Medical Center also provides geriatric long-term care, hospice, and palliative care. It maintained an average daily census of 120, had a 74.3 percent occupancy rate, had 733,512 outpatient visits, and served over 80,000 enrolled Veterans during fiscal year (FY) 2014.

III. Specific Allegations of the Whistleblower

1. The facility's failure to leak test flexible endoscopes in the DC VAMC Ear, Nose, and Throat (ENT) Clinic potentially placed thousands of patients at risk of exposure to infection; and

2. The facility failed to notify affected patients upon learning of the potential exposure.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of [redacted], Interim Director and [redacted], Clinical Program Manager, both of OMI; [redacted], Director National Program Office for Sterile Processing, (NPOSP); [redacted], Deputy Director, NPOSP; and [redacted], HR Specialist with OAR. VA reviewed relevant policies, procedures, professional standards, reports, memoranda, and other documents listed in Attachment A. We held an entrance briefing with Medical Center and Veterans Integrated Service Network (VISN) leadership, conducted a tour of the ENT and GI suite areas, and convened an exit briefing with Medical Center and VISN 5 leadership on the last day of the visit.

VA initially interviewed the whistleblower via teleconference on March 13, 2015; on site on March 16, 2015, and again on March 19, 2015. We also interviewed the following Medical Center employees on site:

- [redacted], Chief of Staff (CoS)
- [redacted], Associate Director Patient Care Services (ADPCS)
- [redacted], Chief, Sterile Processing Services (SPS)
- [redacted], Chief, Infectious Disease
- [redacted], Chief, Infection Control
- [redacted], Patient Safety Manager
- [redacted], Chief, ENT
- [redacted], Former SPS Chief
- [redacted], Director of Quality Management
- [redacted], Quality Management Coordinator
- [redacted], ENT Nurse Manager
- [redacted], Infection Control Nurse

We also had teleconference calls with two Olympus Representatives.

- [redacted], Olympus Representative
- [redacted], Olympus Manager, Infection Control

V. Findings, Conclusions, and Recommendations

Allegation 1

The facility's failure to leak test flexible endoscopes in the DC VAMC Ear, Nose, and Throat (ENT) Clinic potentially placed thousands of patients at risk of exposure to infection.

Findings

Background

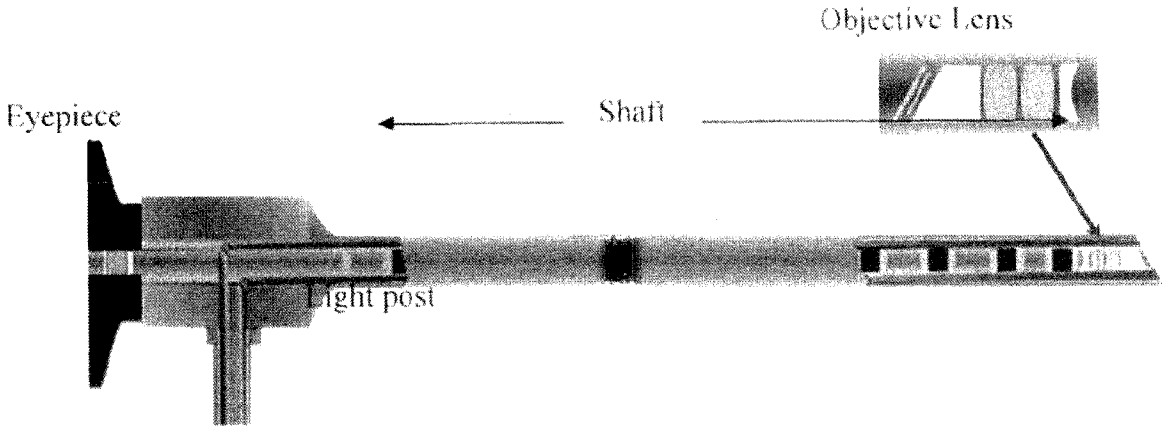
The aims of sterile processing of medical and surgical instruments are to prevent transmission of pathogens to patients, minimize risks to staff, and preserve the value of the items being reprocessed. Sterile processing includes the decontamination, cleaning, and sterilization of instruments. According to the Occupational Safety and Health Administration (OSHA) regulation, decontamination is the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles, and the surface of the item is rendered safe for handling, use, or disposal.[1] Cleaning is the removal of all visible and non-visible soil, and other foreign material from medical

[1] 29 C.F.R. 1910.1030 OSHA Bloodborne Pathogens Standards, Toxic and Hazardous Substances.

devices being processed.[2] Sterilization is the process by which all forms of microbial life including bacteria, viruses, spores, and fungi are completely destroyed.[3]

Physicians use endoscopes to diagnose and treat numerous medical disorders. The incidence of infection associated with the use of endoscopes has been reported as very low (about 1 in 1.8 million procedures).[4] High level disinfectants can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few may survive.[5]

Rigid endoscopes are made of a solid metal tube using lenses for imaging and fiber optics for lighting. Rigid endoscopes do not bend and are used for viewing parts of the body accessible to a rigid piece of equipment. This type of endoscopy equipment is used to view joints, some female reproductive organs, and the ear, nose and throat. Rigid colonoscopes are another example of this type of endoscopy equipment. Operating endoscopes are equipped with irrigation and suction channels, as well as channels for inserting special instruments such as biopsy forceps to obtain tissue samples.



A flexible endoscope's body is sheathed in a specialized flexible covering rather than the stainless steel used for a rigid endoscope. This flexible covering allows the scope to bend as it is inserted into body cavities in ways that a rigid endoscope cannot. Flexible endoscopes allow viewing of interior portions of the body not accessible using a rigid endoscope. There are two types of flexible endoscopes: fiberoptic endoscopes and videoscopes.

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[2] International Association of Healthcare Central Service Materiel Management. Central Service Technical Manual, 7th Edition, 2007, p. 471

[3] International Association of Healthcare Central Service Materiel Management. Central Service Technical Manual, 7th Edition, 2007, p. 501

[4] Schembre DB., "Infectious complications associated with gastrointestinal endoscopy." Gastrointest. Endosc. Clin. N. Am. 2000;10:215-32.

[5] William A. Rutala & David J. Weber, "New developments in reprocessing semicritical items," American Journal of Infection Control, 41 (May, 2013), S60-S66.

A fiberoptic endoscope has an eyepiece lens through which the image is viewed by direct vision or by using a camera connected to the eyepiece lens. A videoscope has the camera incorporated into the flexible fiberscope; it is equipped with a video chip positioned at the distal end of the endoscope ("chip on a stick") to transmit the image directly to the video monitor.[6] As with rigid endoscopes, some flexible endoscopes are equipped with internal channels for irrigation, suction, or the collection of biopsy specimens. Flexible endoscopes that do not contain such conduits are referred to as "non-channel" scopes.

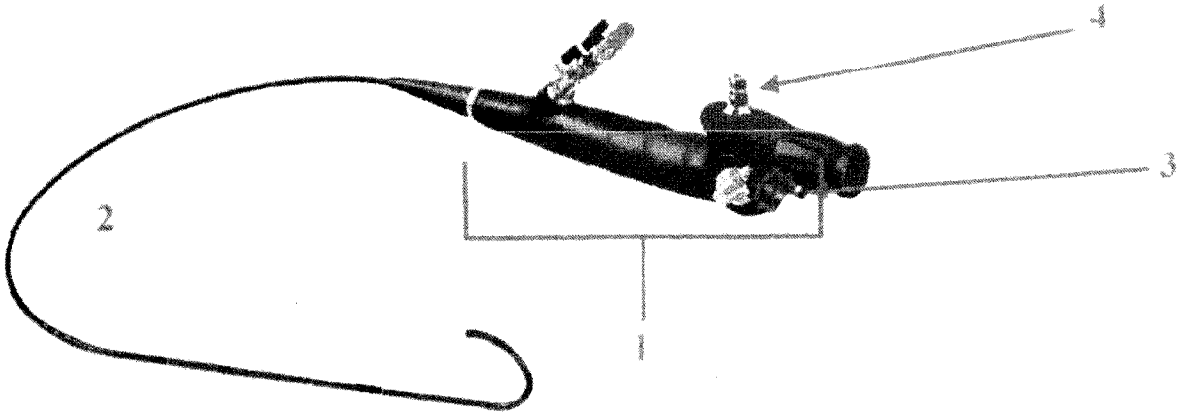
There are four main sections of a flexible endoscope (see figure):

1. Control Body. This portion of the scope remains outside the patient and acts as a handle for the surgeon; it also contains the deflecting controls, biopsy port, air and water channels and eyepiece (if it is not a video scope).

2. Insertion Tube. This is a flexible tube containing the following items:
   a. fiberoptic bundles that transmit light from the light source to the internal body structure;
   b. image bundles that carry the image from the body structure to the eyepiece or attached camera; and
   c. in some cases, channels for the passage of operative instruments, suction, irrigation and insufflation,

3. Deflection Controls. These are used by the surgeon to steer the lenses in various directions within the internal body structure and manipulate the bending section at the distal tip.

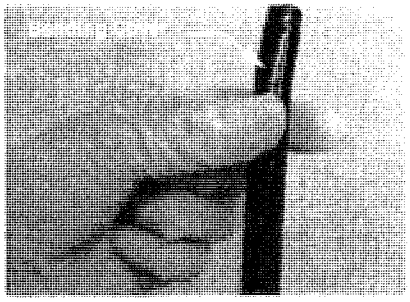
4. Light-guide Connector Unit. This section connects to the light source. In the case of a GI scope, this would also include the suction and insufflation source.



[6] The Care and Handling of Rigid and Flexible Scopes (An Online Continuing Education. Pfiedler Enterprises © 2013.
http://www.pfiedler.com/ce/1231/files/assets/common/downloads/The%20Care%20and%20Handling%20of%20Rigid%20and%20Flexible%20Scopes.pdf

The ENF-GP (Attachment B) is a complete, portable, rhino-laryngo fiberoptic endoscope that provides large and bright high-resolution images.[7] This tool enables visualization of the upper aerodigestive tract.[8] It is solely used for visualization and therefore does not contain internal channels. Because it is a closed or non-channel system, it cannot be used to collect washings or biopsy specimens, and thus there is no pathway for the patients' blood or other bodily fluids to get inside the instrument.

The bending section of the endoscope contains a thin balloon within its walls permitting the directional movement of the tip of the instrument. The bending cover is made from a thin, pliable material. The bending section of an endoscope tends to be the most common site of damage requiring repair, as it is the most manipulated and angulated portion of the instrument. Cracks or tears in the bending cover can permit the invasion of body fluids or disinfectant solutions beneath the outer sheath (Attachment B. #1 Bending Section).[9]



A bending cover that has a hole in it or that has been ruptured will most likely cause damage to internal components because disinfectant fluid will penetrate the opening during reprocessing. Fluid invasion is a flexible endoscope's worst enemy because of this potential for damage to the instruments' delicate internal components. Fluid can enter a scope wherever the integrity of the instrument is compromised. Small holes are difficult to detect during routine visual inspection. It is most often impossible to determine how and when a hole was created. If a fluid invasion goes undetected, the resulting problems may include image stains, foggy images, or electrical malfunction.[10] In fact, approximately 80 percent of all image problems are caused by fluid invasion.

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[7] Olympus ENF-GP Flexible Fiberscope. © Olympus 2015. http://www.olympus-europa.com/medical/en/medical_systems/products_services/product_details/product_details_12544.jsp

[8] The aerodigestive tract refers to the combined organs and tissues of the respiratory tract and the upper part of the digestive tract (including the lips, mouth, tongue, nose, throat, vocal cords, and part of the esophagus and windpipe). http://www.cancer.gov/dictionary?cdrid=44811

[9] The Care and Handling of Flexible Endoscopes, A Clinical Education Study Guide #6, presented by Steris © 2004 http://csao.net/files/pdfs/Flexible%20scope%20handling.pdf

[10] Endoscope Leak Tester Rusnani Bt Yahya, 2013 http://www.psa.edu.my/cmet/publications/Digest/ENDOSCOPE%20LEAKAGE%20TESTER.pdf

Leak Testing

Leak testing will demonstrate if there is a hole in the outer covering or inner lining of the flexible endoscope that could result in fluid invasion. Each flexible endoscope manufacturer recommends using the manual leakage tester designed for its particular flexible fiberscope.

Modern endoscopes are airtight, allowing the internal cavities to be pressurized in order to detect leakage. Because an undetected leak can cause extensive damage to the internal components of the endoscope, it is important to perform a leak test after every procedure before the scope is immersed in water.[11] Thus leak testing is the first step performed before proceeding with any cleaning steps (see figures below). The nature of the main structural components of the endoscope allows pressure testing to be effective, but also means that fluid entering one area of the scope can travel along the entire internal structure. If there is a leak in the flexible covering, fluids can seep into the conduits that house the viewing optics, the light fiber optics, and the cables that control the distal tip. If that happens, the endoscope can be further damaged and may require more costly repairs.

[11] Pathogens of Concern: Keeping our Patients Safe in Endoscopy. Copyright © 2007-2015 Claire Maguire, All rights reserved. http://educationaldimensions.com/eLearn/pathogens/reproprocedure.php.

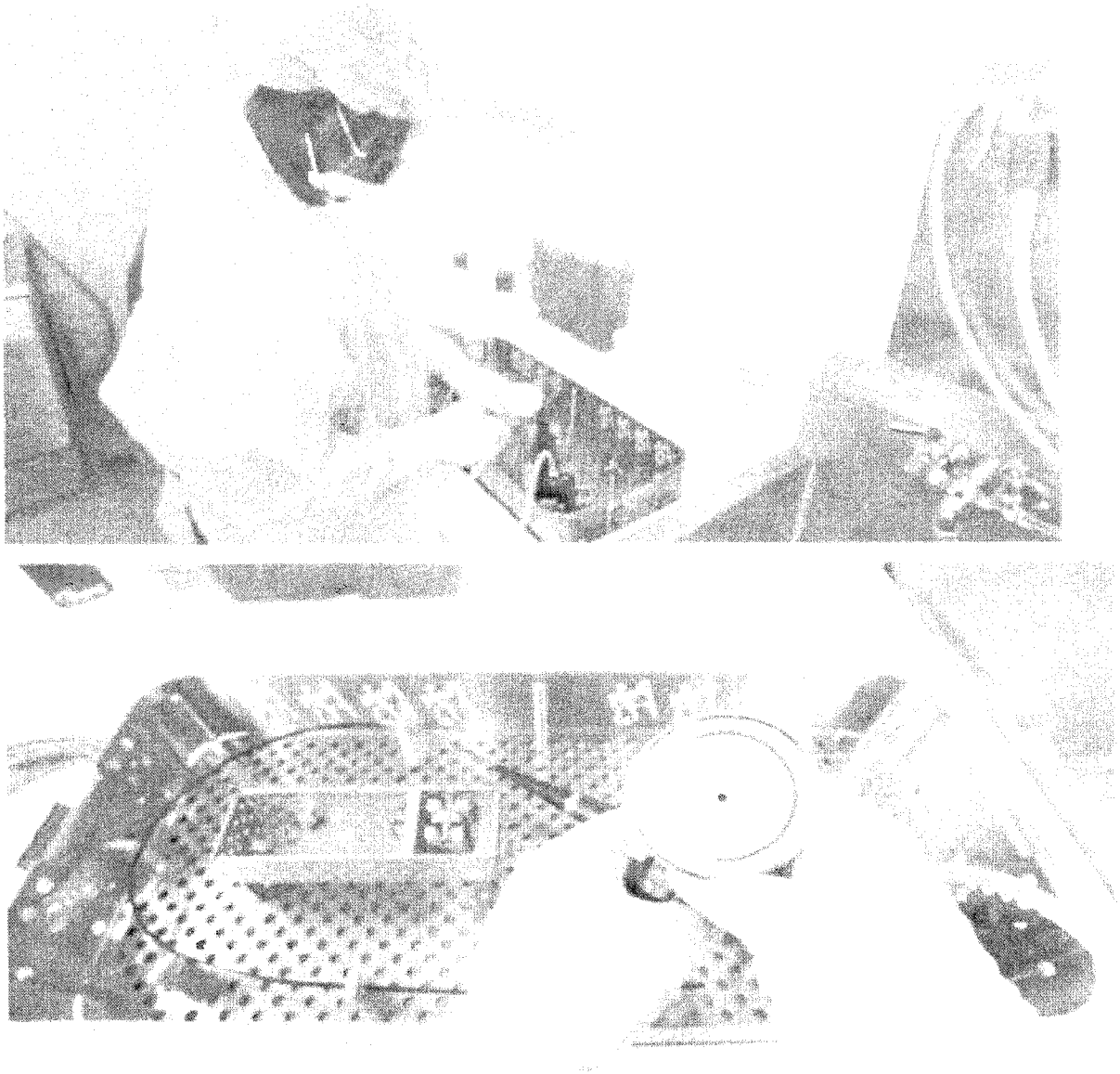

Figure: Performing a Manual Leakage Test

Cross-infection can be a risk if a leak is not detected before the instrument is used again on another patient. However, if a leak is undetected, and the endoscope is then cleaned and disinfected (i.e., undergoes sterile reprocessing), cleaning and disinfection fluids have access to the same areas beyond the leak as biological materials, thereby killing bacteria and viruses.[12]

[12] EndoNurse: The Authority for the Continuing advancement of Endoscopic Nursing. Leak Testing, March 30, 2007. http://www.endonurse.com/articles/2007/03/scope-leak-testing.aspx .

According to the Olympus ENF-GP Instruction Manual, (2006), agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the Food and Drug Administration as "sterilant/disinfectants" which are used according to specific time, temperature, and dilution procedures to achieve high-level disinfection. The CDC recommendation for the use of high-level disinfection of contaminated devices indicates that high-level disinfectants are effective at inactivating HBV-, HCV-, HIV- or TB and other pathogens that might contaminate semi-critical devices.[13] (Semi-critical devices are those which come in contact with non-intact skin or mucous membranes).

Guidelines

In 2008, the Centers for Disease Control (CDC) modified their national guidelines for endoscope reprocessing based on patient and staff safety concerns. The changes pertained to cleaning nasopharyngeal rigid and flexible endoscopes, as well as staff training standards, competencies, scope storage standards and personal protective equipment.[14] The American Academy of Otolaryngology adopted these CDC guidelines in 2009.[15]

CDC's 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities presented evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the health care environment. This document superseded the relevant sections contained in the 1985 Centers for Disease Control (CDC) Guideline for Handwashing and Environmental Control. The 2008 guideline resulted from a review of all articles published in the scientific literature under the headings of disinfection or sterilization (focusing on health-care equipment and supplies) from January 1980 through August 2006.[16]

The Whistleblower's Contribution

The whistleblower worked in the medical intensive care unit prior to moving to the ENT clinic in 2008. Shortly after his reassignment in August of that year he rewrote all of the ENT clinic's standard operating procedures (SOPs), including one that describes how to conduct leak testing. He stated that leak testing was not being performed until then, although he acknowledged that even before 2008 the instruments had been cleaned and disinfected according to the prevailing standards at the time. The whistleblower informed VA that he was also instrumental in the purchase of a leak tester in 2008, which led to the discovery of several endoscopes with leaks. These scopes were sent

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[13] Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. http://www.cdc.gov/hicpac/Disinfection_Sterilization/3_2contaminatedDevices.html

[14] Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee, Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

[15] Head and Neck Nursing. *High level disinfection of flexible nasopharyngoscopes, videolaryngoscopes, and rigid nasal endoscopes: An evidence-based approached.* (31). Spring 2013, 7-13.

[16] Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, Executive Summary and Methods.

out to the vendor for repair and later returned and reprocessed for use. (Refer to purchase of Leak Tester (Attachment E; Biomed Repair Log, Attachment F).

The whistleblower stated that to his knowledge, some of the endoscopes have been in service since 1995. He also stated that prior to the rewriting of the SOPs, any damaged endoscopes would have been sent to the vendor for repair. Upon receiving damaged endoscopes, the vendor would check the endoscopes by leak testing and manual inspection and repair them as needed. After repair, the vendor would return the scopes to the facility for reprocessing prior to use in the next patient. The whistleblower could not provide specific knowledge of any Veteran who had been directly exposed to infection or had any adverse health outcomes resulting from endoscopic examinations.

Since he incorporated leak testing into the SOPs, the ENT clinic staff has been processing the equipment properly according to appropriate standards. (ENT Policy Dated February 14, 2007 Attachment D).[17] After each patient use, the scope is first cleaned and then leak tested in the reprocessing room, in accordance with the clinic's SOP. If there is an air leak, the endoscope is taken out of service and a work order is placed to have the scope repaired. It is then disinfected and sent to the biomedical department who in turn, sends it to the vendor for repair.

VA inspected the reprocessing rooms in both the ENT clinic and GI suite. We donned the personal protective attire that staff is required to wear during reprocessing, then observed the procedures employees used to reprocess instruments while asking them specific questions about the instrument(s) they were reprocessing at that time. We found the staff knowledgeable on all accounts. We also reviewed the cleaning instructions for each instrument as it was being reprocessed, checked to make sure the equipment used for reprocessing (such as leak testers, cleaners, solutions, timers, etc.), was appropriate according to each endoscope's SOP, and verified that all SOPs were up to date.

Assessment of the Potential for Risk to Public Health and Safety

In an effort to identify any evidence of harm to Veterans that might have resulted from improper ENT scope reprocessing procedures prior to 2008, VA interviewed a number of key Medical Center employees, including the physician who is the chief of infectious diseases and the hospital epidemiologist; the Chief of Staff (CoS); the Patient Safety Manager; the Quality Manager; the Associate Director for Patient Care Services/Nurse Executive; the Chief of the ENT Service; and the ENT Clinic Nurse Manager. We also reviewed Infection Control Committee (ICC) minutes and the results of previous Joint Commission accreditation surveys of the Medical Center.

The hospital epidemiologist, who has been with the Medical Center for 25 years, stated that he was not aware of any data that would indicate patient exposure to bacterial or viral infections in the ENT clinic or from an ENT procedure. He also indicated that any such matter of concern would be recognized through routine infection control monitoring

[17] The whistleblower was unable to provide VA with a copy of his rewritten SOP.

and discussed at quarterly ICC meetings. He did not remember any staff member from the ENT clinic, nursing, or Medical Center Leadership approaching him or discussing this concern with him. He did recall receiving information from VA Central Office several years ago about a clinical disclosure related to prostate biopsy devices, but stated that the Medical Center had followed the guidance provided by Central Office and the recommendation has been closed.[18]

VA reviewed ICC minutes from March 2010 to December 2014. (Copies of committee minutes prior to 2010 have been archived and were not available for review.) The reports summarized the entire Infection Control program facility-wide including bloodborne pathogen exposure, TB surveillance, sterile monitor use, reusable medical equipment, and flash sterilization.[19] Our review of ICC minutes during this period revealed one incident involving an endoscope and found that the Medical Center took appropriate action, as follows:

> The ICC minutes dated November 19, 2011 note, "There was one episode regarding scope use in the operating room (OR). The scope was used after the reprocessing expiration date on the scope's tag. The scope was properly reprocessed but the time frame for storage was expired. There was no concern of transmission of organisms. All cases, scope care and records were reviewed. The system for labeling and storing scopes was revamped. Staff was re-educated, and has demonstrated correct scope care and storage."

The CoS, who has been with the Medical Center for 25 years, stated that at no time during his tenure had any staff member voiced concerns directly or indirectly to him regarding the reprocessing of endoscopes by the ENT service. He went on to state that ICC minutes and reports have not demonstrated evidence of an increase in infections among patients resulting from ENT procedures.

The Patient Safety Manager, in her present position since the summer of 2007, reviewed patient safety reports that have been filed by employees using the Medical Center's web-based reporting system. Her department investigates significant patient safety concerns by conducting detailed analyses, using standard health care quality improvement methods such as Root Cause Analysis (RCA) and Healthcare Failure Mode Effects Analysis (HFMEA), to determine the underlying causes of preventable errors and identify potential harm to patients. After reviewing the patient safety database, she confirmed that the Medical Center had not conducted a RCA or HFMEA on the reprocessing of Olympus non-lumen ENT scopes since 2008, indicating that this had not been identified as an area of concern.

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[18] VA OIG Report No. 09-01784-146, *Healthcare Inspection; Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities* (June 16, 2009). Page 5.

[19] Bloodborne pathogens are infectious microorganisms in human blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV). Occupational Safety & Health Administration website. https://www.osha.gov/SLTC/bloodbornepathogens/index.html

An Infection Control nurse who had been SPS Chief from 2006-2010 stated she was very familiar with the flexible nasopharyngoscope, and that at no time did the whistleblower or any other staff member approach her with any infection control concerns regarding the use of the instrument. During her tenure as SPS Chief, the Medical Center underwent much scrutiny and many accreditation inspections by The Joint Commission. We reviewed the findings of the Joint Commission surveys, both announced and unannounced, from October 2005 to April 2014. Our review identified one finding in the April 2014 survey related to infection control:

> Observed in Tracer Activities:[20]
>
> "In the Endoscopy/GI lab, along with department staff and leaders, observed that the bottom section of two storage cabinets for endoscopy scopes had very visible dust, debris, and dried droplets of solution, that could potentially contribute to an increased risk for infection."

The Medical Center's response to The Joint Commission to address the issue:

1. All scope cabinets were cleaned immediately after finding. Cabinets are to be cleaned weekly or when visibly soiled per process checklist. This corrective action was implemented immediately, with monitoring and weekly checks beginning April 15, 2014.
2. Compliance has been sustained. Infection Control is conducting monthly monitoring and reviewing documentation of weekly cleaning. Infection Control, Quality Management, and Patient Safety have added this to their weekly random rounds.
3. July 17, 2014, the Joint Commission accepted the evidence of standards compliance with the identified measure of success as submitted. The same process is in place with a noted compliance level greater than 95 percent.

The present Chief of Quality Management has been in that department since 2008. During that period she has served as a standing member of the Reusable Medical Equipment Committee, assisted with the Committee's restructuring, and participated in reusable medical equipment tracers. She stated she is familiar with the endoscope in question and indicated that as long as proper cleaning and high level disinfection was completed properly, the risk for cross contamination is minimal.

Since her arrival in 2012, the Associate Director for Patient Care Services has not been made aware of any quality concerns regarding the reprocessing of scopes. She told VA that if there had been any patterns or trends of Veterans developing ENT-related infections or an increase in ENT-related admissions, she and Medical Center leadership

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[20] The tracer methodology, in effect since 2004, uses information from the organization to follow the experience of care, treatment, or services for a number of patients through the organization's entire health care delivery process. Tracers allow surveyors to identify performance issues in one or more steps of the process, or interfaces between processes. The Joint Commission, *Facts about the Tracer Methodology*, January 7, 2014. http://www.jointcommission.org/facts_about_the_tracer_methodology/default.aspx

would have been made aware by Infection Control and the ENT staff. She has not heard of any complaints, formally or informally, nor had evidence been presented to the Reusable Medical Equipment Committee, the Infection Control Committee, or any other hospital committee whose minutes are reviewed by the executive leadership team. The Medical Center is in the process of consolidating the reprocessing of all endoscopes and other reusable instruments into a single area.

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.

She stated that 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.

The ENT Chief acknowledged the whistleblower's instrumental role in the guideline process: his changes did clarify the cleaning process, and now all ENT residents are educated on the cleaning process during their initial clinic orientation. She stated that at no time had the whistleblower voiced concerns regarding the cleaning of endoscopes to her.

The ENT Nurse Manager began working in the ENT clinic at about the same time as the whistleblower in 2008. At first, she focused on the daily needs (staffing, equipment, and management) of the clinic while the whistleblower focused on daily operations. She informed VA that since ENT is a nurse-run clinic, it is the responsibility of the ENT nurse to ensure the proper reprocessing of the endoscopes.

We also interviewed a technical representative of the Olympus Corporation, which manufactures the flexible nasopharyngoscopes in question. The Olympus representative stated that the pre-2008 version of the user's manual for non-lumen nasopharyngoscopes included instructions for conducting leak tests, but did not state that using a leaking endoscope can present an infection control risk. She indicated the document does state that insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing

the next procedure with the endoscope. The 2006 edition of the endoscope manual, Chapter 5.2, page 32, paragraph one states,

> "Failure to properly clean and high-level disinfect or sterilize endoscopic equipment after each examination can compromise patient safety. To minimize the risk of transmitting diseases from one patient to another, after each examination the endoscope must undergo thorough manual cleaning followed by high-level disinfection or sterilization."

We reviewed the Food and Drug Administration's (FDA) medical devices database and found one recall on the endoscope (ENF-GP) dated November 1, 2011. The user facility had been performing manual cleaning, and reprocessing the device in an automatic endoscope reprocessor, but continued using it after observing that the device would not hold pressure during leak testing. The endoscope was returned to the manufacturer for an evaluation that confirmed the presence of an air leak from a cut found on the exterior of the bending section. A more proximal area of the scope was flattened from what appeared to be crush damage. Foreign material was visible in the cut area of the bending section. The device was refurbished and returned to the facility. Also, instruction manuals that provided detailed instructions on reprocessing were supplied. The conclusion was that the damage appeared to be due to user error.[21] There have been no other recalls of this specific endoscope in the FDA data base going back to 2002, nor were any found in a search of VA's National Center for Patient Safety database (Attachment H).[22]

In summary, all employees interviewed stated that ENT endoscopes are properly reprocessed after each use and before being used in another patient. The whistleblower himself said that he did not have any concerns regarding the reprocessing of the scopes, nor was he aware of any problems related to the reprocessing of the endoscopes prior to his assignment to the ENT Clinic in 2008, other than the lack of leak testing.

Allegation 2

The facility failed to notify affected patients upon learning of the potential exposure.

To support his assertion that he had raised his concerns about the risk to patients associated with the ENT Clinic's failure to conduct leak testing prior to 2008, the whistleblower produced a single email message that he had sent to the ENT Service Chief and Nurse Manager (with courtesy copy to the applicable Infection Control nurse) on August 18, 2008 (Attachment G). He acknowledged that he did not receive replies to his email message, did not follow up with subsequent emails, and did not subsequently

[21] MAUDE Adverse Event Report: Olympus Medical Systems Corporation Olympus Rhino-Laryngofiberscope. FDA. 02/28/2015. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2393238

[22] The VA National Center for Patient Safety was established in 1999 to develop and nurture a culture of safety throughout the Veterans Health Administration. It is a part of the VA Office of Quality, Safety and Value. http://www.patientsafety.va.gov/index.asp

raise his concerns to a higher level via email or other means. None of the recipients that we interviewed recalled responding to the whistleblower or receiving follow up communication from him. Although the whistleblower indicated that he had been directed not to send further email messages, his supervisors denied doing so or discouraging him in any way from bring his concerns forward. On the contrary, many employees in the supervisory chain acknowledged the whistleblower's tireless efforts to update the ENT Clinic's SOPs with the latest standards. In fact, the ENT Nurse Manager wrote a recommendation for special advancement for the whistleblower on the basis of his performance.

The whistleblower notes that in 2009, the VA Office of the Inspector General (OIG) issued a report on the failure by several VA locations to properly clean and maintain endoscopes. The OIG found that VA facilities had not complied with management directives to ensure compliance with reprocessing of endoscopes, "resulting in a risk of infection disease to veterans." The OIG notes that CRAABs (Clinical Risk Assessment Advisory Boards) were convened in response to each incident outlined in the report, and in many cases, notification of patients occurred. The whistleblower argues that the situation at the Medical Center is substantially similar to the examples in the OIG report, and therefore warrants a full review and notification pursuant to the VA's policies.[23]

In its June 16, 2009 report, (No. 09-01784-146), the OIG concluded that several VA locations did not follow proper procedures for cleaning and maintaining endoscopes. The Washington, DC VA Medical Center was not among the facilities sampled for the initial report.

The OIG initial report reviewed gastrointestinal colonoscopy reprocessing at the Bruce W. Carter VAMC, in Miami, FL and the Tennessee Valley Healthcare System - Murfreesboro campus. ENT endoscopy reprocessing was reviewed at the third facility visited, Charlie Norwood VAMC in Augusta, Georgia. The cleaning review addressed the cleaning of GI endoscopes, and noted that, unlike the nasopharyngoscopes in question, these scopes contain a hollow lumen. Therefore the cleaning and maintenance procedures are different.

On November 4, 2008, a patient in the ENT clinic at the Augusta VAMC questioned the method by which a nurse was cleaning a laryngoscope. The patient, who had already had his endoscopic procedure, read instructions on the box of disposable sanitizing cloths being used by the nurse. The instructions stated that they should not be used as a means to clean equipment that comes in contact with mucous membranes. At the time of the event, ENT endoscopes were cleaned in the ENT clinic by nursing staff; they were not undergoing sterile reprocessing using high level disinfectant solutions. An ENT physician reported the patient's concern to the Chief of Surgery, who then notified the medical center's epidemiologist and Chief of SPD. On November 5, 2008, the Chief of Surgery closed the ENT clinic pending completion of a preliminary

[23] OSC Letter to Secretary Veterans Affairs, February 5, 2015.

investigation. The ENT clinic resumed seeing patients on November 12 following staff training.[24]

On June 24, 2009, the Acting Under Secretary for Health, Veterans Heath Administration, testified about the OIG's findings before the Committee on Veteran's Affairs in the United States Senate.

> "In relation to the inadequate processing of endoscopes, that is, those steps taken to disinfect at a high level endoscopic equipment and prepare it for further use, VA has taken local and national actions to better understand how this could happen and to ensure it does not happen again. We are committed to an open and honest assessment of our policies and procedures. While we never want to worry patients unnecessarily, we believe patients have a right to know about important information that could potentially affect their health. VA's policy requires disclosure to patients of any adverse events related to their health care that causes or may potentially cause harm. VA has notified patients about even those events that may not be obvious or severe or those that pose only a minimal risk to a patient's health. The probability that anyone was harmed as a result of our inadequate reprocessing at these four facilities is very low.
>
> "The disclosures we are making to Veterans are based on the very small potential for harm. At present, there is no definitive evidence to suggest that the positive tests we have found so far are the result of inadequate reprocessing of endoscopy equipment. In this country, many adults who are infected with Human Immunodeficiency Virus (HIV), Hepatitis B and C have not been tested and would not be aware that they are infected. In recent weeks VA has been testing many patients who have never been tested before. As a result, we would expect some of these patients would test positive. No matter how low the likelihood that any disease occurred due to suboptimal scope disinfection, VA will care for patients regardless of the source of infection. There were other facilities where there was inadequate reprocessing of endoscopes but, after review, it was determined that the risk of harm to patients at these facilities was so remote that it did not justify informing patients."[25]

In the follow-up inspection, August 3–6, 2009, reprocessing locations at 128 medical facilities were inspected. An additional facility with one reprocessing unit was inspected on August 12. All 129 facilities were compliant with respect to SOPs. All facilities had adequate documentation of demonstrated competence for reprocessing staff except for the White River Junction VA Medical Center, Vermont.[26] Since then, all of the VHA

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[24] Department of Veteran Affairs, Office of the Inspector General Report No. 09-01784-146, *Healthcare Inspection, Use and Reprocessing of FlexibleEndoscopes at VA Medical Facilities* (June 16, 2009).

[25] Gerald M. Cross, MD, FAAFP, Acting Under Secretary For Health, Veterans Health Administration, U.S. Department Of Veterans Affairs , testimony before The Committee On Veterans' Affairs, United States Senate, June 24, 2009. http://www.va.gov/OCA/testimony/svac/090624JP.asp

[26] VA OIG Report No. 09-02848-218, *Healthcare Inspection, Follow-UP Colonoscope Reprocessing at VA Medical Facilities* (September 17, 2009).

recommendations in OIG report 09-01784-146 have been closed.[27] There were no recommendations pertaining to improper procedures at this Medical Center.

The name "CRAAB" was changed to "Clinical Review Board" (CRB) when the applicable VHA Handbook was revised in 2012.[28] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, (October 2, 2012) defines "disclosure of adverse events" as the forthright and empathetic discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future.

VA recognizes three types of adverse event disclosure:

(1) Clinical Disclosure of Adverse Events. Clinical disclosure of adverse events is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care.

(2) Institutional Disclosure of Adverse Events. Institutional disclosure of adverse events (sometimes referred to as "administrative disclosure") is a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse.

(3) Large-scale Disclosure of Adverse Events. Large-scale disclosure of adverse events (sometimes referred to as "notification") is a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue. This process also generally includes public notification and direct communication to key stakeholders.

If the CRB determines that there is negligible risk of harm, no further action is required regarding large-scale disclosure and the issue is closed.[29]

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[27] VA verified with the Director, Management Review Service that the VHA recommendations from the 2009 initial report has been closed.

[28] The CRB is a multi-disciplinary board, convened at the request of the Principal Deputy Under Secretary for Health, in response to adverse events that may pose a clinically-significant risk of harm to multiple patients (or members of patients' families), but the probability of harm and/or the severity of the potential harm cannot be determined. The CRB uses a transparent and systematic process to consider whether disclosure is ethically warranted in light of the indeterminate risk.

[29] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012.

Conclusions

- VA **was not able to substantiate** that the Medical Center's failure to leak test flexible endoscopes in the ENT Clinic prior to August 2008 potentially placed thousands of patients at risk of exposure to infection.

- Although leak testing was not instituted until August 2008, VA found that flexible fiberoptic nasopharyngoscopes have been properly cleaned and disinfected after each patient use in accordance with established guidelines and the manufacturer's recommendations, both before and since that time.

- If a leak had developed in the external sheath of a flexible fiberoptic nasopharyngoscope before leak testing was instituted, but the instrument then underwent sterile processing, the next user would most likely have recognized evidence of damage to internal structures such as poor image quality or other malfunction. Even in the absence of such evidence, the high-level disinfectant fluids used in sterile processing would follow the same path via the leak site as any potentially biohazardous materials, and would inactivate them.

- VA **did not substantiate** the allegation the facility failed to notify affected patients upon learning of the potential exposure. Other than one cautionary email sent by the whistleblower to ENT Clinic managers on August 18, 2008, there is no record of further communication regarding these concerns, nor is there evidence that an adverse event occurred, such as a higher than expected number of deleterious health outcomes among ENT Clinic patients due to exposure to infectious agents.

- Although there is no clear evidence of a substantial and specific threat to public health and safety resulting from the Medical Center's failure to perform leak testing prior to 2008, VHA should employ its existing methods for assessing the probability of patient harm and whether patient disclosure is ethically warranted.

Recommendation to the Medical Center

1. Request an assistance visit from the National Program Office for Sterile Processing for guidance on consolidating sterile processing operations.

Recommendation to VHA

2. 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.

VI. Summary Statement

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and

specific danger to public health and safety. In particular, the OGC has provided a legal review, and the OAR has examined the issues from an HR perspective to establish accountability, when appropriate, for improper personnel practices. VA found no violations of law, rule or regulation.

Attachment A

29 C.F.R 1910.1030 OSHA Bloodborne Pathogens Standards, Toxic and Hazardous Substances.

American Association of Medical Instrumentation (AAMI) Standards. (www.aami.org)

Association for peri-Operative Registered Nurses (AORN) Perioperative Standards and Recommended Practices, 2012.

Department of Veterans Affairs, Office of the Inspector General Report No. 09-01784-146, *Healthcare Inspection; Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities* (June 16, 2009).

Department of Veterans Affairs, Office of the Inspector General Report No. 09-02848-218, *Healthcare Inspection; Follow-Up Colonoscope Reprocessing at VA Medical Facilities* (September 17, 2009).

Disinfection and Decontamination: Principles, Applications and Related Issues, CRC Press; Boca Raton, FL, © 2008; Taylor and Francis Group, LLC.

International Association of Healthcare Central Service Materiel Management. Central Service Technical Manual, 7th Edition, 2007.

Medical Center Cleaning and High Level Disinfection of Non-Lumen Endoscopes, ENT Clinic, February 14, 2007.

Medical Center Infection Control Minutes, March 2010 to December 2014.

Medical Center Sterile Processing Services (SPS) Competency Folders.

Medical Center SPS Infection Control Policy and Procedures, February 26, 2014.

Memorandum from Patient Safety Director, May 12, 2015.

Olympus ENF TYPE GP Rhino-laryngofiberscope Instruction Manual, 2006.

Olympus ENF-GP product brochure.

The Centers for Disease Control (CDC). *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008. (www.cdc.gov).

The Joint Commission Official Accreditation Reports, Washington DC VAMC, October 2005 – April 2014.

United States Food and Drug Administration Medical Devices Database. http://www.fda.gov/MedicalDevices/default.htm

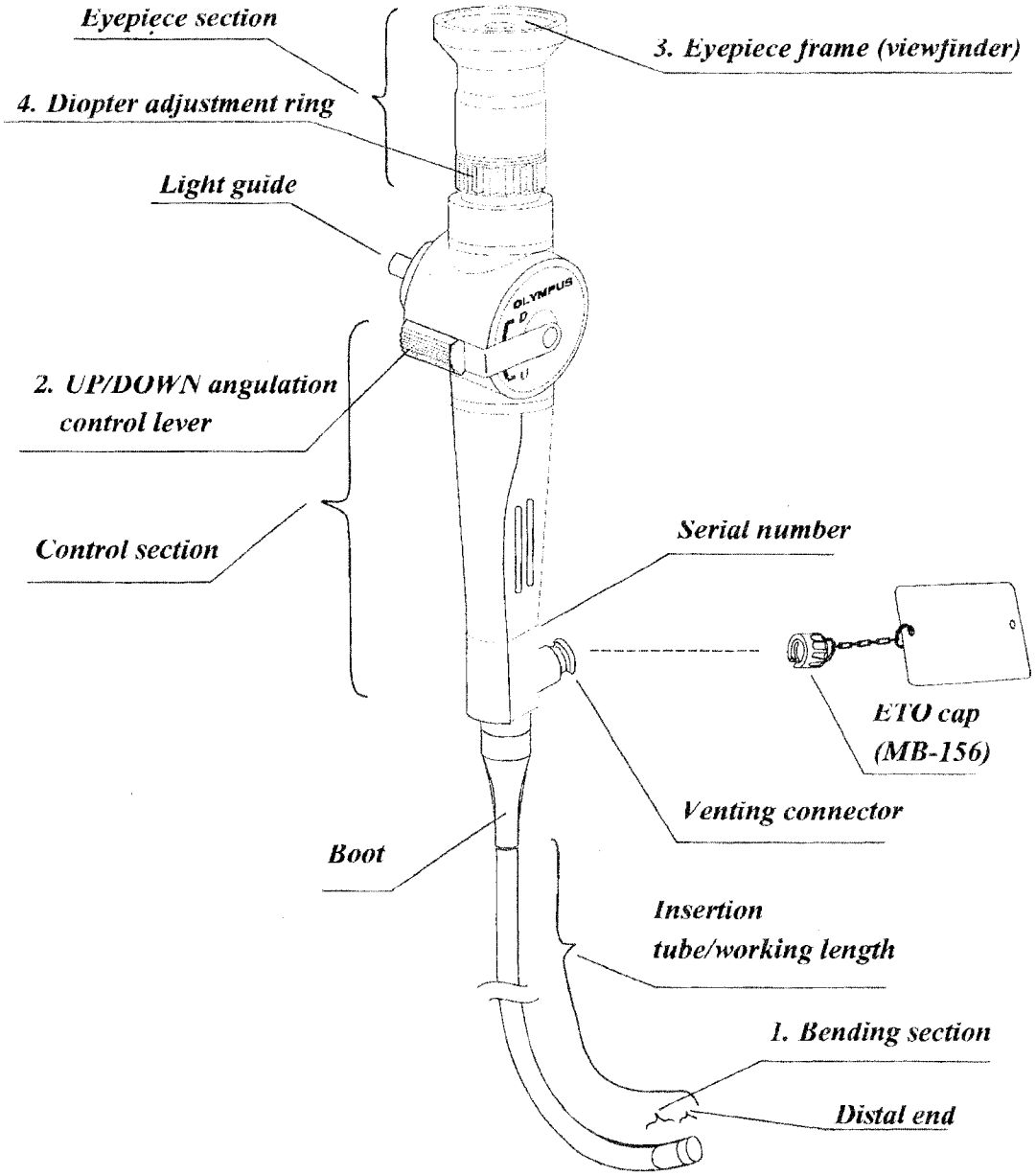
VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, 2009.

VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients* (October 2, 2012).

Attachment B

Chapter 2 Instrument Nomenclature and Specifications

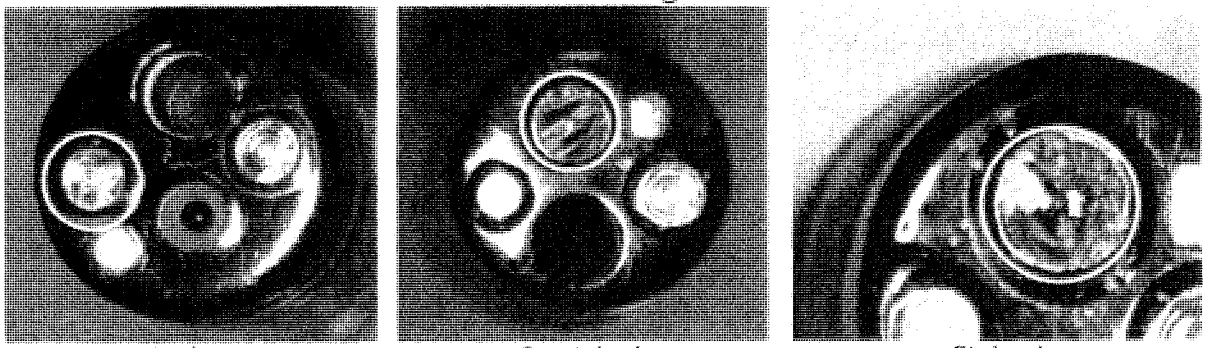
2.1 Nomenclature



From the Olympus ENF TYPE GP Rhino-laryngofiberscope Instruction Manual, 2006, p. 9

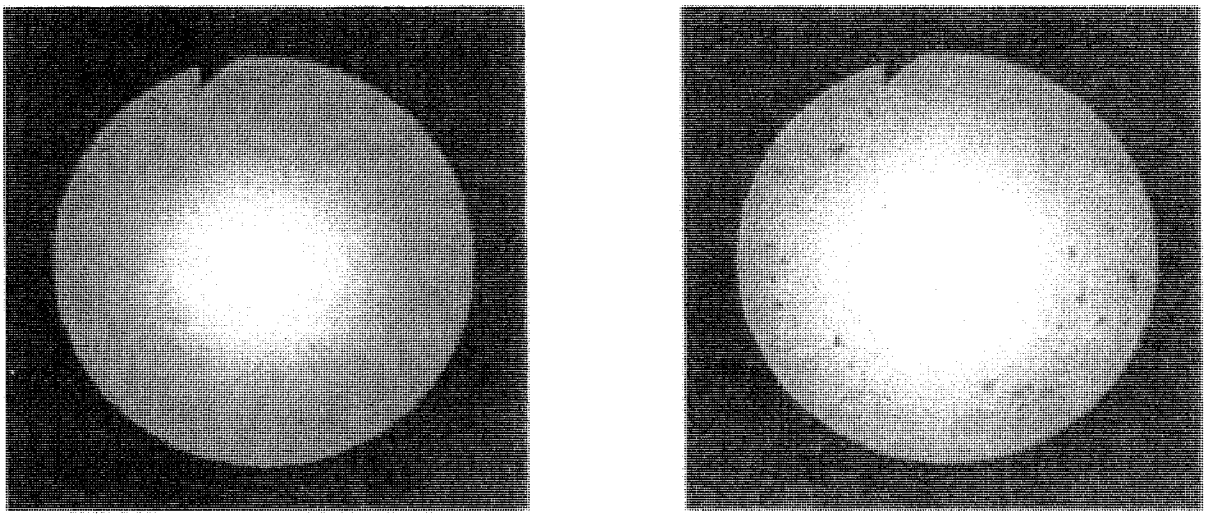
Attachment C

Distal End Lens – Damaged and Residue



Broken | Scratched | Stained

Light Post with Broken Fibers



If black dots cover more than 30% of the light post, the endoscope should be sent in for repair or replacement. The greater the blackened area, the dimmer the light will be during the procedure.

Attachment D

Procedure
LEAK TESTING PROCEDURE:
If the endoscope is Olympus ENF Type GP or any other flexible endoscope, perform leak testing. Leak testing ensures that the endoscope is waterproof. (For further information, refer to the operating instructions for leak testers, located in the 2B223 endoscope cleaning room.)
For the Olympus MU-1 Leak Tester, the detailed procedure is as follows:
1. Fill a basin with water deep enough to allow the endoscope to be completely immersed.
2. Insert the leak tester connector onto the output socket of the Olympus MU-1 Leak Tester Maintenance Unit Instrument.
3. Confirm that the leak tester is emitting air by gently depressing the pin located inside the leak tester's connector cap, and listening for the sound of released compressed air.
4. Attach the leak tester to the venting connector on the endoscope.
5. With the leak tester connected, immerse the endoscope in water and observe for approximately 30 seconds while angulating the bending section of the endoscope. Confirm that there is no location on the endoscope from which a continuous series of bubbles emerges.
6. Remove the endoscope from the basin.
7. If no bubbles were observed in step 5 above, turn the Olympus MU-1 Leak Tester Maintenance Unit Instrument off and disconnect the leak tester from the Olympus MU-1 Leak Tester Maintenance Unit Instrument. Wait 30 seconds or until the bending section contracts to its pre-expansion size. Then disconnect the leakage tester's connector cap from the venting connector.
8. If bubbles **WERE** observed in step 5, the MU-1 should remain attached to the endoscope and powered on during the entire cleaning and disinfection process. After cleaning and disinfection is complete, a work order should be generated and the endoscope is sent to Biomedical Engineering for repairs.
9. Dry the leak tester as needed with a clean towel.
(The above leak testing procedure is based on Olympus Instructions Rhino-Laryngofiberscope, Olympus ENF-GP, pages 38-39.)
For the Welch Allyn leak tester, the procedure is as follows:
1. Fill a basin with water deep enough to allow the endoscope to be completely immersed.
2. **BEFORE IMMERSION** verifies that the leak tester's connector and the endoscope vent port are dry. Secure the leak tester's connector to the endoscope's vent port. Proper alignment will require alignment of the air vent pin and clockwise rotation.
3. Attach the leakage tester to the venting connector on the endoscope. Tighten the pressure release valve on the handle of the leak tester.
pressurize into the red zone, as this may damage the endoscope.

Procedure
5. Observe the gauge pressure to determine if the indicator remains in the green zone. If the indicator drops from the green zone rapidly, a major leak is indicated. (Double check to make sure the pressure release valve on the handle of the leakage tester has been tightened).
6. If a major leak is indicated, do not immerse the scope into water. Instead, place the scope in a biohazard bag and contact Welch Allyn for instructions on how to proceed.
7. If no major leak was detected during the prior step, with the leakage tester connected and the scope pressurized with the gauge indicator in the green zone, immerse the endoscope in clean water and observe for approximately 30 seconds while angulating the bending section of the endoscope. Confirm that there is no location on the endoscope from which a continuous series of bubbles emerges.
8. Remove the endoscope from the basin.
9. If no bubbles were observed in step 7 above, depressurize the scope by turning counter clockwise the pressure release valve on the handle of the leak tester and wait for the gauge indicator to reach zero. Wait 30 seconds or until the bending section contracts to its pre-expansion size. Then disconnect the leakage tester's connector cap from the venting connector.
10. If bubbles **WERE** observed in step 7, the leak tester should remain attached to the endoscope and pressurized during the entire cleaning and disinfection process. After cleaning and disinfection is complete, a work order should be generated and the endoscope is sent to Biomedical Engineering for repairs.
11. Dry the leakage tester as needed with a clean towel.
(The above leak testing procedure is based on RL-150 Rhinolaryngoscope and LX-150 Light Source Operating Instructions, Welch Allyn, pages 8-9)

Procedure
PREPARE ENZYMATIC CLEANING SOLUTION
Use fresh solution each time an endoscope is processed:
1. Measure one ounce of Endozime AW Plus enzymatic cleaning solution into a basin.
2. Add 2 gallons of water.
3. Use enough water to completely submerge the endoscope. If more is needed, mix at a ratio of one-half fluid ounce of Endozime AW Plus to one gallon of water.

Procedure
GROSS CLEANING OF THE ENDOSCOPE
1. Immediately after patient use, pre –clean and place endoscope in large biohazard bag.
2. Transport dirty endoscope to workroom 2B223, rinse with tap water and wipe off any visible organic matter using gauze.
3. Perform leak testing as described above.
4. Completely submerge endoscope into freshly-made enzymatic solution.

Procedure
5. Set the timer to 5 minutes.
6. After 5 minutes, remove endoscope from enzymatic solution and rinse under running water.
7. Dry endoscope thoroughly with clean towel.
8. Inspect endoscope to ensure it is completely dry.
9. Discard enzymatic cleaning solution by pouring it down the drain.

Procedure
QUALITY CONTROL (QC) OF CIDEX OPA (HIGH-LEVEL DISINFECTION)
Quality Control (QC) must be done before each use, and when new solution is prepared to ensure effective concentration for high level disinfection.
1. Dip entire indicating pad of strip into Cidex OPA solution for one second and remove. Do not shake strip.
2. Remove excess solution from indicating pad by standing it upright on paper towel.
3. Read result at 90 seconds. DO NOT EXCEED 90 SECONDS.
4. Positive result: entire indicating pad will be PURPLE. Solution is potent.
5. Negative result: indicating pad will be ANY COLOR OTHER THAN PURPLE. Solution is not potent. Discard solution. DOT NOT USE.
6. Record result in the log.
Note: Cidex OPA solution in the soaking bins is potent for 14 days, or until daily QC test strip indicates a color other than purple. Discard after 14 days even if test is potent (positive QC result, purple). See "Disinfection of Equipment Using Cidex OPA" policy for complete details regarding QC testing.

Procedure
DISINFECTION WITH CIDEX OPA SOLUTION
1. Place clean and completely dry endoscope in Cidex OPA solution and replace lid.
2. Set the timer to 12 minutes. (time required for disinfection)
3. After 12 minutes, remove endoscope and rinse with three 1000 cc bottles of sterile water.
4. Dry endoscope using lint-free clean laparatomy sponge.
5. Place disinfected endoscope in clear plastic bag; transport to examination room.
6. Hang disinfected endoscopes in clean endoscope cabinet.

Procedure
C. SPS Responsibility Decontamination Area
N/A

Procedure
D. SPS Responsibility – Assembly Area
N/A

Procedure
– OFF-TOUR USE OF NON-LUMEN ENDOSCOPES
In the event that a non-lumen endoscope is used on the weekend, a holiday, or after hours, the physician will rinse the endoscope in tap water and wipe it with any clean lint free cloth, such as gauze or a lap sponge – and will then place the endoscope into a biohazard bag and leave it in the designated bin in the ENT Clinic Endoscope Cleaning Room (2B223).

3.0 Appendices

None

4.0 References

http://www.onesourcedocs.com/filename/Olympus_ENF_GP_RhinoLaryngofiberscope_GR_6496_r27_200612.pdf/03514760013254507 39/1364836724/oneSOURCE.html

http://www.onesourcedocs.com/filename/Olympus_ENF_GP_RhinoLaryngofiberscope_GR_6496_r27_200612.pdf/03514760013254507 39/1364836789/oneSOURCE.html

http://www.onesourcedocs.com/filename/Olympus_ENF_V2_VISERA_RhinoLaryngo_Videoscope_GE_3411_r16_200702.pdf/00834480013254508 29/1364836878/oneSOURCE.html

Attachment E
Receipt of Leak Tester

OLYMPUS

Olympus America Inc.
Customer Service
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610
TEL (800) 848-9024
Fax (800) 228-4963

QUOTATION

NO. 110145-Q0-0

Please refer to this number on all correspondence or when confirming order

CUSTOMER INFORMATION

Customer: V.A. Medical Center
Attention: [redacted]
Address: 50 Irving St. N.W.
3Rc Floor
Washington, DC 20422
Phone: (202) 745-8000 [redacted]
Fax: (000) 000-0000
E-Mail: [redacted]

OLYMPUS SALES REP

Name: [redacted]
Sales Representative/ Sales Trainer
Home Page: http://www.olympusamerica.com
Phone: (800) 645-8100 [redacted]
Fax: (800) 228-4963
E-Mail: [redacted]

TERMS AND CONDITIONS

Effective: 08/20/2008	Expires: 9/20/2008
Terms: Net 30 days, subject to Olympus credit approval	F.O.B. Destination
Tax: When Applicable	Delivery: 30/45 days After Receipt of Order

Warranty: Generally, Capital equipment manufactured by Olympus is warranted against manufacturers defect for a period of one year. See Limited Warranty for details.

Price Terms: The quoted prices are based on the Olympus - VA-Veterans Affairs contract# V797P-4282A which expires 02/29/2012 (MP Products) or contract# V797P-4282A which expires 02/29/2012 (SP Products)

FINANCIAL OPTIONS

1. Net 30 Days/Interest 1 1/12% monthly, subject to Olympus credit approval
2. American Express, Visa and MasterCard accepted
3. Olympus offers a wide range of services from financing/leasing options, including a usage-based program that matches payments to procedures performed to a comprehensive service agreement

QUOTATION DETAIL

	Item / Description	List Price	Your Price	Qty	Extended Price
1	MB-155: Leakage tester for OES/EVIS endoscopes	233.00	182.48	1 ea	182.48
2	MAJ-1219: SUCTION ADAPTER FOR PEF-V	32.00	28.64	1 ea	28.64
3	MAJ-210: BF scope sterile, single-use disposable biopsy valve (20 pcs.) for EVIS 180/160/240/200 and OES 60/40/30 (20 pcs.)	72.00	56.39	1 ea	56.39

I. Price quotes and the total package prices are for listed items only.
II. Changes, additions or deletions from this package quotation may cause pricing adjustments.
III. Service manuals and additional operator manuals are not included and may be ordered by contacting the Customer Care Center at (800) 848-9024.

List Total Price:	$337.00
Your Total Price:	$268.51

PERIOPERATIVE SERVICES SUPPLY REQUEST

SPECIALTY: Otolaryngology Head and Neck Surgery (ENT)

VENDOR: Welch Allyn Inc VENDOR PHONE # 800-535-6663

Catalog Number	Complete Item Description and size ----	Unit of Issue	Qty	price	IFCAP Number
86545	LEAK TESTER	ea.	1	317-	10/10/08

Date Returned: 9/8/08 Emergency (Yes) No

Reason for Request: Need to test RL-150 endoscope

[redacted]

Attachment F

Equipment Biomed Repair Log

DATE OUT	SN		WO #	DATE IN	SCOPE TYPE	PROBLEM
				3/13/2009	HEAD LAMP	MISSING PARTS cant
6/25/2008		2704598	RA080625-011		OLY ENF GP	MISSING LIGHT GUIL
		2806287		9/2/2008	OLY ENF GP	FAILED LEAK TEST
		2704601		9/2/2008	OLY ENF GP	FAILED LEAK TEST
		2805289		9/2/2008	OLY ENF GP	FAILED LEAK TEST
		2704599		9/2/2008	OLY ENF GP	FAILED LEAK TEST
				9/25/2008	OLY ZERO DEG	
9/3/2008	A7595A		RA080903-034	11/12/2008	OLY 30 DEG	DARK SPOTS
9/3/2008	A011427		ra080903-031	9/16/2008	WA RL150	TIP BENT & DARK
9/4/2008	A70942A		ra080905-029	11/12/2008	OLY 70 DEG	DARK FIELD VIS
10/3/2008			RA081003-017	10/20/2008	HEAD LAMP	FRAYED CORD
10/8/2008			RA081008-016	11/20/2008	HEAD LAMP	NOT WORKING
11/6/2008		1200017	RA081106-016	2/6/2009	PEF V	REPL AIR/WATER & S
2/3/2009		2805281	RA090203-018	3/6/2009	OLY ENF GP	FAILED LEAK TEST
2/10/2009		2704603	RA090210-007	3/6/2009	OLY ENF GP	FAILED LEAK TEST
2/10/2009		2805286	ra090210-024	3/6/2009	OLY ENF GP	FAILED LEAK TEST
2/20/2009			ra090220-006	3/13/2009	HEAD LAMP	FRONT LENS DETAC
2/20/2009	A7595A		RA090220-005	10/26/2009	30 DEG SCOPE	DARK IMAGE
5/12/2008		2805287	ra090512-013	6/1/2009	OLY ENF GP	FAILED LEAK TEST
7/22/2009				7/22/2009	WELCH AL RL150	
9/22/2009		2704602	RA090922-025	12/1/2009	OLY ENF GP	FAILED LEAK TEST
10/15/2009		2805289	RA091015-012	12/1/2009	OLY ENF GP	FAILED LEAK TEST
11/9/2009	A70940A		RA091109-13		OLY ZERO DEG	MARKED "BROKEN"
11/9/2009		2805281	RA091109-014	1/4/2010	OLY ENF GP	FAILED LEAK TEST
NOTE: 5/26 PICKED UP ZERO DEG SCOPE FROM THE OR, SER #A70940A						
3/25/2010	A7094A		RA100325-018		OLY ZERO DEG	FUZZY IMAGE
4/2/2010		2805281	RA100401-028	4/30/2010	OLY ENF GP	FLEXES 1 DIRECTIOI
6/16/2010	A7094A		RA100616031		OLY ZERO DEG	FUZZY IMAGE
7/6/2010			Ra100706-015		OLY MAJ-922 LIGHT	ELECTRICAL CONTA
ON 7/6/10 WHEN I RETURNE FROM VACATION OLY 30 DEG SCOPE HAD BEEN RETURNED FROM E						
9/23/2010		2805281	RA100924-025	2/24/2011	OLY ENF GP	FAILED LEAK TEST
9/23/2010	A70940A		RA100924-024	3/11/2011	OLY ZERO DEG	POOR IMAGE
2/24/2011					OLY ZERO DEG	BURR
3/22/2011		2805281	RA110322-015	11/16/2011	OLY ENF GP	FAILED LEAK TEST
3/22/2011			RA110322-016	ok	WA HEADLIGHT	ELECT CONTACT INT
9/6/2011		2805286	ra110906-017	11/15/2011	OLY ENF GP	SPOTS IN IMAGE
9/12/2011	A7595A		RA110912-026	12/5/2011	30 DEG SCOPE	Dark image
11/10/2011		2805291	RA111110-008	BACK	OLY ENF GP	FAILED LEAK TEST
4/20/2012		2704803	RA120420-006	BACK	OLY ENF GP	Damaged insertion tub
7/19/2012		2704599	RA120719-006	BACK	OLY ENF GP	FAILED LEAK TEST
7/19/2012	688 EE1275212		RA120719-011	BACK	W/A Headlight	Lens loose
9/6/2012		2704803	RA120906-025	12/11/2012	OLY ENF GP	FAILED LEAK TEST
9/27/2012		2805289	RA120927-019	2/11/2013	OLY ENF GP	FAILED LEAK TEST
10/4/2012	A7595A		RA121004-040	11/4/2012	OLY 30 DEG	Scope is dark
10/23/2012		2805281	RA121023-019	12/2/2012	OLY ENF GP	Poor image + bunched
11/15/2012	A70940A		RA12115-011	11/28/2012	OLY ZERO DEG	Burr on tip
11/15/2012	A70941A		RA12115-009	11/28/2012	OLY 30 DEG	Scope is dark

Attachment G

ENT Scope Cleaning

Monday, August 18, 2008 2:50 PM
From:
"Leahy John C." <John.Leahy@va.gov>
To:
[redacted]
Cc:
[redacted]

An Olympus rep. specializing in endoscope care visited us as planned on Friday. [redacted] and [redacted] attended. This followed my 8/6 visit to the Bronchoscopy Lab and 8/13 visit to the GI Lab to observe their scope cleaning procedures

Both the GI Lab and Bronchoscopy Lab employ automated scope cleaners for their submersible scopes. ENT, which may see up to 45 patients in a clinic day with perhaps 20-30 scope cleanings, does not.

That being said, except for the possible issue of room ventilation, our existing ENT Clinic scope cleaning procedures appear to be entirely satisfactory for cleaning of our rigid endoscopes.

For our flexible non-channeled endoscopes, there is only one area in which our existing procedure is seriously out of line with Olympus recommendations: leak testing. For ENF Type GP scopes (and actually all Olympus flexible scopes) Olympus recommends that each scope be leak tested each time it is cleaned. (See Section 7.2 of the ENF Type GP Instructions for Use.) The GI and Bronch Labs leak test their scopes prior to each cleaning. The ENT Clinic never leak tests scopes. If a scope develops a leak, it can damage the scope and also present an infectious disease risk to patients on whom the scope is subsequently used, according to the Olympus rep.

[redacted] has cautioned me that we may not change our cleaning procedures on our own initiative because our procedures have been approved by "higher ups". However, I recommend that we seek permission to add the following line immediately after the tap water rinse:

"For flexible endoscopes, prior to submersion into enzymatic solution, leak test the scope using an Olympus MU-1 leak tester."

I gave the Olympus rep a tour our procedure rooms and he was able to find that we had an MU-1 leak tester apparently set up as a light source for the video tower in the senior resident's room. (It certainly does LOOK like a light source.) We do not however, have any of the 2 attachments needed to make the MU-1 functional; namely, a power cord and a connecter hose #MB-155. I obtained a power cord from Biomed this morning, but we will have to order the MB-155 connector hose from Olympus if we want to use the MU-1 leak tester. We will also need to have electrical outlets placed in the cleaning room. Unless I hear an objection, I will place an order for that MB-155 and also place a work order for the necessary electrical outlet.

Additionally, our procedure will have to provide for processing flexible endoscopes in the event that they fail leak testing. My understanding is that they may not be shipped dirty for repair – nor would we want to do that. Neither do we want them to be damaged by submersion during cleaning. The answer, according to the Olympus rep., is to leave the leaking scope attached to the MU-1 leak tester while goes through the usual cleaning process, and then send it for repair.

Our current ENT Clinic cleaning and disinfection procedure does not allow for the presence of our Olympus PEF Type V channeled endoscope. This is an old scope and we do not use it very often, but if we are going to use it at all we need a procedure to clean and disinfect it appropriately. The Olympus rep. was kind enough to provide me with an electronic-media user's manual for this scope, which I am attaching to this email. Chapter 7 deals with cleaning and disinfection.

As far as it goes, our current ENT Clinic procedure is appropriate for this type of scope says our Olympus rep.; however, there are a number of additional steps that need to be adopted. These additional steps are necessary to leak test the scope (exactly as with the non-channeled flexible scopes), clean and disinfect the suction valve, the air/water valve, and clean and flush all channels. According to our Olympus rep., we should also order a suction cleaning adapter #MAJ-1219, which the Olympus PEF Type V manual lists in Section 7.5 as necessary for manual cleaning but seems to be missing from our scope kit.

I will order the MAJ-1219 cleaning adapter.

At the Friday meeting, these are the additional steps that the Olympus rep. recommended:

1. Remove the Suction Valve and Air/Water valves and clean with a channel opening cleaning brush and enzymatic detergent.

2. During the initial gross cleaning, use a channel cleaning brush to brush all channels as specified in the "Brushing the Channels" section of Chapter 7 of the PEV Type V manual.

3. After brushing the channels, flush them with 150 cc of detergent. We could use portable suction for this, as they do in the Bronchoscopy and GI labs.

4. After the enzymatic detergent soak (15 minutes) flush all channels with 150 cc of water and then blow out with air.

5. When the scope is submerged in the Cidex bath, draw up Cidex into the channels so they can be disinfected.
6. After the Cidex bath, flush the channels with water, then 70% alocohol, and then blow out with air.
7. Hang scope to dry.

As for ventilation of the cleaning room, it is my understanding that Cidex may fumes may lead to complaints of bronchitis, asthma-like symptoms, and development of scent allergies. Equipment manufacturer PCI Medical states that air in the room should be exchanged 10 times per hour via wall vents. Cidex OPA instructions (under "Precautions") state that local exhaust hoods or ductless fume devices should be used if adequate ventilation is not otherwise provided. [redacted] has been kind enough to arrange for air circulation in our cleaning room to be measured (with the door closed, I assume). I would note, however, that PCI medical cautions that ceiling vents may actually make the fume situation worse rather than better if they are positioned so that they draw fumes from the Cidex across the face of the cleaning personnel. I would submit to you that our ceiling vent is EXACTLY so situated.

Assuming that we continue with our non-automated scope cleaning procedure, I think we should consider purchase of something like a GE18E PCI Medical ductless vapor control device (see pcimedical.com), for which I have obtained a quoted a price of $2,185.

Attachment H

PATIENT SAFETY ALERTS & ADVISORIES ON REPROCESSING ISSUES

Date Issued	Alert or Advisory	Product - Device
December 22, 2008	Alert	Improper set-up and reprocessing of flexible endoscope tubing and accessories AL09-07
March 31, 2008	Alert	Improper reprocessing of flexible endoscope biopsy valves AL08-13
March 12, 2008	Alert	STERIS C1160 Universal Flexible Processing Trays used with the STERIS System 1 Sterile Processing Systems AL08-11
October 30, 2007	Alert	Updated Haag-Streit reusable tonometer tip (prism) reprocessing instructions for U.S. customers AL08-03, addendum to AL07-02 and AL07-06
March 7, 2007	Alert	Reprocessing instructions for Haag-Streit reusable tips (prisms) used to measure intraocular pressure AL07-06, addendum to AL07-02, amended by AL08-03
January 31, 2007	Advisory	Reprocessing of resectoscope system's working elements AD07-03
October 26, 2006	Alert	Reusable tips (prisms) for tonometers used to measure intraocular pressure AL07-02, amended by AL07-06
April 3, 2006	Alert	Transrectal ultrasound transducer assembly, Models 8808 and 8551, manufactured by B-K Medical Systems, Inc., Wilmington, MA PDF Version [AL06-11]
October 5, 2005	Alert	Olympus 180 series endoscopes and Steris Quick Connects PDF Version [AL06-01]
February 13, 2004	Alert	Connectors for Sterilization of all Gastrointestinal Fiberoptic Endoscopes Word Version [no Alert # provided]
March 6, 2003	Advisory	Olympus EXERA™ Gastrointestinal Endoscopes Word Version [no Advisory # provided]
March 8, 2002	Alert	Bronchoscopes Manufactured by Olympus America Word Version [no Alert # provided]

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

March 8, 2002

Item: Bronchoscopes manufactured by Olympus America, Inc. Affected models are: BF-40, BF -P40, BF-1T40, BF-3C40, BF -XP40, BF -XT40, BF -240, BF -P240, BF-1T240, BF-6C240, BF-160, BF-P160, BF-1T160, BF-3C160, BF -XT160, per manufacturer's letter.

Specific Incident: A loose biopsy port can trap bacteria in a spot that the usual disinfecting process may not reach. Bronchoscopes are not steam-sterilized like other instruments, but are cleaned with chemicals and washed in a special machine. An unnamed private hospital reported an unusually high number of cultures performed on lung secretions collected from Olympus bronchoscopes that were positive for pseudomonas. Epidemiologists traced the problem to the Olympus bronchoscopes, which were picking up bacteria from one patient, shielding them from the disinfectants and transferring them to the next patient exposed to the scope.

Action:
1. If you have not already done so, immediately (within 24 hours) identify all units affected by this alert. Remove them from service and test them for a loose portal following Olympus' procedure (attachment 1).
2. If you detect any looseness in the biopsy channel port, discontinue using the affected bronchoscope, notify Olympus via fax (Attachment 2) and return it to Olympus per their directions (Attachment 3) for immediate upgrade.
3. If the unit is not affected, it can be used. However, Olympus requests that it be returned for a biopsy port housing upgrade when practical.
4. Finally, if you have affected units, review relevant patient records to determine if there is a pattern of increased pseudomonas infections associated with use of these bronchoscopes and report positive findings to [redacted], VAMC Cincinnati (negative reports not required).

Additional Information: Olympus mailed notices in November 2001, with a second notice February 27, 2002.

Source: Manufacturer

Contact: [redacted]. You can also contact [redacted], VA Center for Engineering & Occupational Safety and Health (CEOSH) at [redacted].