



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Colonoscope Reprocessing
at Multispecialty
Community-Based
Outpatient Clinics



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Executive Summary

The VA Office of Inspector General (OIG) conducted a national review to assess specific training and selected elements of colonoscopy reprocessing at the 10 multispecialty community-based outpatient clinics (CBOCs) that performed colonoscopies on-site.¹

Colonoscopy, as with any invasive procedure, carries some risk and the possibility of infection acquired from improperly or incompletely cleaned medical devices.² Properly trained staff and adherence to cleaning and storage protocols are essential to minimizing the risk of infection.

Colonoscopes must be thoroughly cleaned in accordance with the manufacturers' instructions that apply to each model. The structural complexity of colonoscopes, specifically the number of hollow channels and guidewires exposed to the inside of the colon, adds to the difficulty of ensuring that colonoscopes are free of biological debris, such as blood or tissue. After cleaning, colonoscopes must be checked for any remaining biological material that could pose a risk to patients. Colonoscopes are then stored under specific parameters to ensure that they are dry and not exposed to environmental contamination.

For staff assigned to reprocess colonoscopes, the Veterans Health Administration (VHA) requires specific training during initial orientation and monthly continuing education for staff to maintain their technical knowledge. The Chief of Sterile Processing Services (SPS) is responsible for oversight of SPS staff training. VHA also has strict requirements for the disinfection and storage of colonoscopes. Failure to properly train staff places patients at elevated risk for infection or other adverse outcomes related to improperly cleaned equipment. Incompletely or incorrectly processed or stored equipment may also result in avoidable adverse outcomes.

The OIG reviewed oversight of SPS training and documentation, colonoscopy reprocessing, and environmental monitoring in SPS areas.

OIG Findings and Recommendations

The OIG found deficiencies in the training and oversight of SPS staff assigned to colonoscopy reprocessing. The OIG reviewed training documentation of 37 employees at the 10 CBOCs. Of the 37 employees, 16 were governed by a VHA requirement to complete initial training within 90 days of hire. Eight of those 16 (50 percent) SPS staff did not complete required training during initial orientation prior to reprocessing colonoscopes. Service chiefs at 7 of the 10 CBOCs

¹ Multispecialty CBOCs deliver two or more specialty care services on-site, in addition to primary and mental health care.

² A colonoscopy is a type of medical procedure that enables a provider to see the inside of the colon to identify colon cancer. Colonoscopies can be performed in an outpatient setting.

(70 percent) did not ensure that training documentation was completed. The OIG did not identify a common reason for incomplete training documentation, but noted that of the nine service chiefs interviewed (one was responsible for two CBOCs), six had been in the position for less than one year, and two of the six were in interim or acting roles.

SPS staff did not receive continuing education through required monthly in-services at 2 of the 10 (20 percent) CBOCs. The OIG found that supervisors did not ensure that staff attended monthly in-services when SPS staff were organizationally aligned under other clinical services due to a lack in awareness of the requirement for in-services. Lack of training can create a knowledge gap that results in improperly reprocessed equipment and compromised patient safety.

Although training records were incomplete, the OIG determined that CBOC SPS staff reprocessed and tracked colonoscopes according to VHA requirements. In addition, the OIG found that the CBOCs met VHA requirements for continuous environmental monitoring.

The OIG made two recommendations to the Under Secretary for Health related to initial SPS training and continuing education.³

Comments

The Acting Under Secretary for Health concurred with the recommendations and provided an acceptable action plan (see appendix B). The OIG will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
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³ Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge, who had the authority to perform the Under Secretary's functions and duties. Effective January 20, 2021, he was appointed to Acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

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Abbreviations

CBOC	community-based outpatient clinic
NPOSP	National Program Office for Sterile Processing
OIG	Office of Inspector General
SOP	standard operating procedures
SPS	Sterile Processing Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a national review to evaluate the training and oversight of the Veterans Health Administration's (VHA) Sterile Processing Services (SPS) staff assigned to perform high-level disinfection of colonoscopes in multispecialty community-based outpatient clinics (CBOCs). The OIG also assessed certain aspects of colonoscopy reprocessing and examined the maintenance and storage of colonoscopes.

Background

Colonoscopes and Colonoscopy Reprocessing

An endoscope is a flexible fiber-optic tube with a light and a camera at the end that is used to conduct examinations of parts of the body such as the colon and can be used to remove tissue for testing (see figure 1).¹ A colonoscopy is a type of endoscope that is used specifically to examine the inside of the colon and is reused for multiple patients.² Because colonoscopes come in contact with mucous membranes (the colon), they require special cleaning and disinfection procedures (reprocessing) to remove biological debris and reduce bioburden ("the number of microorganisms on a contaminated object") before they are used for the next patient.³ Failure to properly disinfect colonoscopes carries significant risk for transmission of infectious diseases.⁴

¹ VHA Directive 1116(2), *Sterile Processing Services (SPS)*. March 23, 2016.

² VHA Directive 1116(2). "What Are Reusable Medical Devices?" Food and Drug Administration, accessed on December 30, 2019, <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/what-are-reusable-medical-devices>.

³ VHA Directive 1116(2). Reusable medical equipment is classified into three categories based on its use: critical, semicritical, and noncritical. Colonoscopes are considered semicritical equipment because they come in contact with mucous membranes or non-intact skin and are exposed to bioburden, which is "the number of microorganisms on a contaminated object." Colonoscopes are subject to all training and competency requirements for reusable medical equipment. As this report is limited to colonoscopy procedures, the OIG uses the term colonoscopes when discussing such requirements rather than a more generic term, "reusable medical equipment."

⁴ "Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)," Centers for Disease Control and Prevention, accessed June 2, 2020, <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/introduction.html>.



Figure 1. Picture of endoscope. The circled area is shown in cross section in figure 2.
 Source: Endoscope: Olympus Evis Exera III Olympus GIF-HQ190 and GIF-XP190N Gastrointestinal Videoscope, CF-HQ190L and PCF-HL190DL Colonovideoscope

Because colonoscopes are complex pieces of equipment with multiple ports, channels, and valves that require meticulous attention to detail during reprocessing, manufacturers provide specific reprocessing instructions for each model of colonoscope (see figure 2).⁵

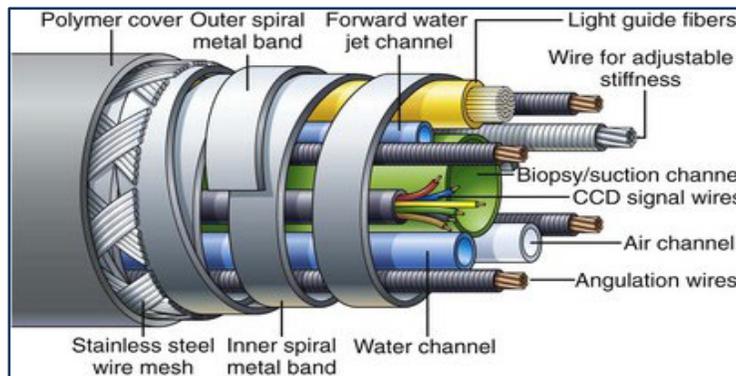


Figure 2. Internal components of a colonoscope. The figure illustrates the number of channels. Each air, water, and biopsy channel is manually brushed, rinsed, and disinfected during reprocessing.
 Source: Clinical Gate® website⁶

Immediately after a colonoscopy, but before SPS staff receive it for reprocessing, the flexible tube of the colonoscope is wiped off and its internal channels are flushed with water and air. During the manual cleaning phase, SPS staff first perform a leak test to identify any physical damage to the colonoscope that could cause it to malfunction. SPS staff then clean the colonoscope manually by brushing and flushing detergent through all its channels, paying close

⁵ VHA Directive 1116(2).

⁶ “How Endoscopes Work,” Clinical Gate®, accessed on January 6, 2020, <https://clinicalgate.com/how-endoscopes-work>.

attention to the air and water channels and instrumentation for tissue removal. SPS staff visually inspect the colonoscope for residual debris and repeat the entire manual cleaning process if any is found.⁷

High-level disinfection is the next phase of reprocessing and includes immersing and flushing the colonoscope with chemicals approved specifically for inactivation and removal of microorganisms that may remain after manual cleaning.⁸ SPS staff then conduct a bioburden test and repeat the steps for high-level disinfection if microorganisms were found. Proper handling and storage under specific environmental conditions complete the process. Documentation of these steps for each colonoscope is essential for quality assurance and patient-equipment tracking purposes.⁹

Environmental Monitoring

VHA requires all SPS areas to have “a monitoring system capable of documenting continuous humidity and temperature.”¹⁰ Air flow direction is controlled to minimize movement of airborne microorganisms from areas containing soiled equipment into clean areas.¹¹ In terms of preventing contamination of equipment, workflow refers to the order in which colonoscopes are received by SPS staff, reprocessed, stored, and later dispensed for patient use. In general, workflow proceeds in one direction; contaminated materials enter the reprocessing area and move to the clean areas where they are stored.¹²

Training and Supervisory Responsibilities

VHA requires training during initial orientation and through continuing education for staff who reprocess colonoscopes. To accomplish this, facility SPS chiefs are responsible for developing and implementing a continuing education and staff development program that begins with initial orientation for new SPS employees and continues with monthly on-the-job training for all SPS employees. Facility SPS chiefs must maintain training folders that are kept in the SPS area for

⁷ Olympus Medical Systems Corporation, *Evis Exera III Gastrointestinal Videoscope and Colonovideoscope Reprocessing Manual*. 2014.

⁸ “A Rational Approach to Disinfection and Sterilization,” Centers for Disease Control and Prevention, accessed September 18, 2020, <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html>. Olympus Medical Systems Corporation. *Evis Exera III Gastrointestinal Videoscope and Colonovideoscope Reprocessing Manual*, 2014.

⁹ “Essential Elements of a Reprocessing Program for Flexible Endoscopes Recommendations of the Healthcare Infection Control Practices Advisory Committee,” accessed on July 15, 2020, <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>.

¹⁰ VHA Directive 1116(2).

¹¹ VHA Directive 1116(2).

¹² VHA Directive 1116(2).

each employee. This includes documentation of orientation courses; certificates of completion; and records of educational hours, continuing education units, or other credits.¹³

Facility SPS chiefs also have supervisory responsibility over SPS staff members who perform reprocessing and for reprocessing activities throughout medical facilities and CBOCs. As such, facility SPS chiefs are responsible for developing standard operating procedures (SOPs) for reprocessing according to manufacturer's guidelines and ensuring manufacturer's instructions for use (instructions) and supplemental SOPs are readily available to staff when reprocessing colonoscopes.¹⁴

CBOC Classifications

A CBOC is an outpatient site of healthcare service located geographically apart from the VHA medical facility with which it is associated. CBOCs may be VA-owned or VA-leased. CBOCs provide healthcare services in primary care, specialty care, mental health care, or any combination. Most CBOCs do not provide care 24 hours a day, and operate from one to seven days per week.¹⁵ VHA classifies CBOCs according to complexity, which is based on numbers and types of specialty services provided and the degree of utilization of those services in terms of encounters (visits).¹⁶

VHA has two classifications for CBOCs: primary care and multispecialty. Primary care CBOCs offer both medical and mental health care. Multispecialty CBOCs deliver two or more specialty care services on-site, in addition to primary and mental health care. Clinic providers may be credentialed and privileged to perform colonoscopies in multispecialty CBOCs that have the necessary infrastructure to support that level of care because these procedures involve minimal sedation of patients.¹⁷

Prior OIG Reports

The OIG published four reports that addressed concerns in the SPS area in the last three years. These reports applied to VHA parent facilities and not to multispecialty CBOCs, which are the subject of this review.¹⁸

¹³ VHA Directive 1116(2).

¹⁴ VHA Directive 1116(2).

¹⁵ The CBOCs that the OIG visited for this review did not operate 24 hours a day.

¹⁶ VHA Handbook 1006.02, *VHA Site Classifications and Definitions*, December 30, 2013.

¹⁷ VHA Handbook 1006.02.

¹⁸ For the purposes of this review, the terms outpatient clinic, clinic, and CBOC are used synonymously.

The OIG report, *Critical Deficiencies at the Washington DC VA Medical Center*, published in 2018, noted deficiencies in SOPs and documentation of SPS staff competencies.¹⁹ As of November 7, 2019, the three recommendations related to SPS deficiencies were closed.

In a second 2018 report, *Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care System*, the OIG made recommendations related to SPS staff training, manufacturers' instructions, SOPs, and competency assessments.²⁰ As of October 23, 2019, the recommendations were closed.

The OIG report, *Deficiencies in Sterile Processing Services and Decreased Surgical Volume at the VA Connecticut Healthcare System*, published in 2019, identified deficiencies in SPS staff competency assessment and training; the resulting recommendation was closed on April 2, 2020.²¹

In a 2020 report, *Deficient Staffing and Competencies in Sterile Processing Services at the VA Black Hills Healthcare System, Fort Meade Campus, South Dakota*, the OIG made a recommendation related to SPS staff competency assessment.²² The recommendation was closed on September 14, 2020.

Scope and Methodology

The OIG initiated a healthcare review on February 18, 2020, and interviewed the Acting Director of the National Program Office for Sterile Processing.²³

The OIG then identified the multispecialty CBOCs that performed colonoscopy procedures on-site from October 1 through December 31, 2019. The OIG conducted site visits on March 10 and March 12, 2020, to 6 of the 10 multispecialty CBOCs that provided colonoscopies. During these six site visits, the OIG inspected colonoscopy procedure rooms and adjacent areas and interviewed SPS chiefs, supervisors, and staff who reprocessed colonoscopes.²⁴

¹⁹ VA OIG, *Critical Deficiencies at the Washington DC VA Medical Center*, Report No. 17-02644-130, March 7, 2018.

²⁰ VA OIG, *Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care System*, Albuquerque, New Mexico, Report No. 17-04593-10, October 31, 2018.

²¹ VA OIG, *Deficiencies in Sterile Processing Services and Decreased Surgical Volume at the VA Connecticut Healthcare System*, Newington, Connecticut; West Haven, Connecticut, Report No. 19-00075-14, November 20, 2019.

²² VA OIG, *Deficient Staffing and Competencies in Sterile Processing Services at the Black Hills Health Care System*, Fort Meade Campus, South Dakota, Report No. 19-09436-108, March 23, 2020.

²³ According to VHA Directive 1116(2), the VHA National Program Office for Sterile Processing is responsible for establishing national policy for reprocessing, training of staff and validation of training, and a quality assurance program for reusable medical equipment reprocessing.

²⁴ VHA Handbook 1006.02, *VHA Site Classifications and Definitions*, December 30, 2013. Multispecialty CBOCs deliver two or more specialty care services on-site, in addition to primary and mental health care.

Given the concerns with travel and to minimize potential spread of COVID-19, the OIG evaluated the four remaining CBOCs virtually through document reviews and telephone interviews with staff at the CBOCs and parent facilities.²⁵ For the four CBOCs, the OIG made assessments based on staff descriptions of workflow and reprocessing in SPS areas.

The OIG reviewed relevant VHA handbooks, directives, and operational memoranda that included requirements of colonoscopy reprocessing, training, oversight of SPS staff who reprocess colonoscopes in multispecialty CBOCs, and methods of monitoring the environment required for decontamination, disinfection, and storage of colonoscopes. The OIG also reviewed facility and CBOC policies and procedures, manufacturers' instructions for colonoscopy reprocessing, training records for CBOC staff who reprocessed colonoscopes, and relevant medical literature.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the review in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Review Results

1. Oversight of SPS Training and Documentation

VHA requires documentation of mandatory Level 1 training and continuing education.²⁶ Facility SPS chiefs are responsible for maintaining documentation of required training prior to the performance of duties.²⁷

According to VHA directive, the Chief of SPS is also responsible for ensuring “that all individuals charged with reprocessing duties are appropriately trained and competency is documented prior to the performance of the assigned tasks. Staff members should participate in ongoing education and training to maintain proficiency.” Training for ongoing competence is to

²⁵ “Travel during the COVID-19 Pandemic,” Centers for Disease Control and Prevention, accessed October 26, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html>.

²⁶ VHA Directive 1116(2).

²⁷ VHA Directive 1116(2).

be developed based on items or procedures that are new or changed, or new technologies, policies, or practices. Ongoing training must also address any identified high-risk and problem-prone equipment, examples of which include colonoscopes.²⁸ Lack of training can create a knowledge gap that results in improperly reprocessed equipment and compromised patient safety.

The OIG noted that SPS chiefs could not provide evidence that SPS staff who reprocessed colonoscopes at multispecialty CBOCs consistently completed initial training or continuing education. Further, when SPS staff were organizationally aligned outside SPS, technical continuing education was not provided to those SPS staff.

Level 1 Training

VHA established specific training requirements to ensure that staff have sufficient knowledge, skills, and abilities to effectively and safely reprocess colonoscopes.²⁹ This Level 1 training must be completed during initial orientation. In an interview, a National Program Office for Sterile Processing (NPOSP) member described the training as foundational because it includes the basic principles of sterilization and disinfection.³⁰

VHA requires that SPS employees hired after March 23, 2016, (the publication date of the current SPS directive establishing the requirement) complete Level 1 training within 90 days of hire and prior to reprocessing equipment independently. Level 1 training is comprised of multiple training modules, and SPS chiefs are responsible for ensuring that all individuals with reprocessing duties undergo Level 1 training. VHA also requires that competency be documented prior to the performance of assigned tasks.³¹

The OIG reviewed training records for 37 SPS staff at the 10 CBOCs. Sixteen of the 37 employees were hired after March 23, 2016, and were required to complete Level 1 training within 90 days of hire. Eight of the 16 (50 percent) completed Level 1 training within 90 days of hire. Of the other eight, five did not complete Level 1 training within 90 days but did complete the training eventually (completion time ranged from 104 to 331 days). The remaining three had not completed Level 1 training as of the date of the review.

The OIG determined that SPS chiefs did not ensure SPS staff completed Level 1 training prior to performance of duties according to documents reviewed. The OIG did not find a common reason for incomplete training documentation but noted recent turnover in SPS Chief positions as a possible reason for noncompliance. Nine SPS chiefs had oversight of the 10 CBOCs (one had

²⁸ VHA Directive 1116(2).

²⁹ VHA Directive 1116(2).

³⁰ VHA Directive 1116(2): The VHA NPOSP establishes policy for processing reusable medical equipment. This program office falls under the VHA Deputy Under Secretary for Health for Operations and Management.

³¹ VHA Directive 1116(2).

responsibility for two CBOCs); six had been in the position for less than one year; and two of the six were in interim or acting roles.³²

Continuing Education

VHA requires that SPS chiefs develop and implement monthly in-services as part of a continuing education program that offers training relevant to the technical reprocessing tasks their staff must complete. In an interview with NPOSP staff, it was emphasized that to enable staff to keep up with reprocessing technology, the training should be ongoing. Most sites produced documentation of monthly in-services. However, at one CBOC, the SPS Chief said that he did not think that SPS staff had to attend monthly in-services. For another CBOC, the facility provided monthly in-service sign-in sheets, but the OIG found that CBOC staff were not listed. At those two CBOCs, clinic leaders informed the OIG that SPS staff were aligned with non-SPS service lines. This resulted in a lack of assurance that all SPS staff were up to date in the technical aspects of their assigned duties and reprocessing colonoscopes effectively. Service chiefs at 7 of 10 CBOCs (70 percent) did not ensure that training was complete.

2. Reprocessing Colonoscopes

The OIG determined that CBOC SPS staff reprocessed colonoscopes according to VHA requirements for manual cleaning, high-level disinfection, and bioburden testing. Additionally, the OIG found that SPS staff at each CBOC had a process for colonoscopy tracking.

Reprocessing colonoscopes involves steps specific to each model that are provided by its manufacturer.³³ VHA requires that manufacturers' model-specific instructions for cleaning and disinfection are readily available to SPS staff in the decontamination area.³⁴ Manufacturers' instructions are lengthy and direct the reader to move forward and back within the document to find instructions on different steps in reprocessing. The SPS Chief is responsible for developing SOPs to simplify the instructions and ensuring that they are readily available to SPS staff at all times.³⁵

The OIG reviewed the SOPs for the 10 CBOCs and found compliance when noting consistency with colonoscopy-specific SOPs and the corresponding manufacturers' instructions.

³² The time in position for these six SPS Chiefs ranged from one day to 10 months.

³³ "Factors Affecting Quality of Reprocessing," Food and Drug Administration, accessed on December 30, 2019, <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/factors-affecting-quality-reprocessing>.

³⁴ VHA Directive 1116(2). A decontamination area is the location in a medical facility where soiled equipment is collected and cleaned.

³⁵ VHA Directive 1116(2).

Additionally, the OIG found through direct observation or by SPS staff statements in virtual site visits that the SOPs and manufacturers' instructions were in the decontamination area as required.

VHA requires bioburden testing of at least 10 percent of each colonoscopy model to verify removal of biological debris after manual cleaning.³⁶ In interviews, staff at the 10 CBOCs said that they performed bioburden testing on each colonoscopy after use. All 10 CBOCs furnished bioburden logs that showed bioburden checks for colonoscopies by serial number, which met or exceeded the VHA requirement. The SOPs at 5 of 10 CBOCs also specifically listed bioburden checks as part of the reprocessing procedure, although VHA does not specifically require this step to be included in SOPs.³⁷

VHA charges SPS chiefs with the responsibility for ensuring that a process is in place to track items that have undergone high-level disinfection.³⁸ Tracking ensures that clinic staff would be able to identify the colonoscopy should an equipment recall or failed bioburden test necessitate action; this also facilitates the identification of patients who underwent a colonoscopy with a particular colonoscopy.³⁹ In 2019, VHA clarified the requirement by designating the use of an electronic tracking system, CensiTrac, but did not establish a timeline for its implementation.⁴⁰ The OIG noted that each of the 10 CBOCs had a process for tracking colonoscopies. Five of the 10 CBOCs used CensiTrac, and the other five CBOCs tracked colonoscopies through manual documentation. In an interview with OIG, the NPOSP Acting Director stated the anticipation that future consistent use of CensiTrac systems would enable the program office to collect and analyze data for instrument tracking nationally.

3. Environmental Monitoring in SPS Areas

The OIG found that the CBOCs met VHA requirements for continuous environmental monitoring. The OIG inspectors reviewed temperature and humidity records for all 10 CBOCs and noted that 9 of 10 CBOCs used automated systems to monitor temperature and humidity and one CBOC recorded monitoring on manual logs.

³⁶ VHA Directive 1116(2).

³⁷ VHA Directive 1116(2).

³⁸ VHA Directive 1116(2).

³⁹ "Essential Elements of a Reprocessing Program for Flexible Endoscopes," Centers for Disease Control and Prevention, *Recommendations of the Healthcare Infection Control Practices Advisory Committee*, accessed on Sept 17, 2020, <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>.

⁴⁰ VHA Directive 1116(2). Deputy Undersecretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services Memorandum." January 1, 2019. Censis ScopeTrac, accessed on May 13, 2020, <https://www.censis.com/scopetrac/>. CensiTrac is a commercial system for tracking surgical instruments and endoscopes through reprocessing and storage.

VHA does not require that SPS staff maintain logs or other daily records of airflow direction; however, at 9 of 10 CBOCS, SPS staff either described ways in which they verified the air flow direction or submitted documentation of airflow monitoring. In site visits, the OIG also observed that equipment processing flowed in the correct direction with colonoscopes being manually cleaned in dirty areas and then moved after disinfection into clean areas for storage or patient care without reentering dirty areas. In interviews during virtual inspections, SPS staff described equipment moving in one direction from dirty areas into clean areas.

Conclusion

Colonoscopes are complex pieces of medical equipment that pose a significant risk of exposure to infectious diseases if they are not cleaned and disinfected properly. The NPOSP emphasized the importance of initial and ongoing training to maintain technological knowledge. The SPS Chief at each VA medical facility is responsible for ensuring that SPS staff assigned to reprocessing duties are appropriately trained prior to the independent performance of their duties and that staff participate in ongoing education and training to maintain technical proficiency.

The OIG found that SPS service chiefs could not provide evidence that SPS staff who reprocessed colonoscopies at multispecialty CBOCs consistently completed initial training as required. Further, the OIG found that when SPS staff were organizationally aligned outside SPS, technical continuing education was not provided to those SPS staff. Lack of training can create a knowledge gap that results in improperly reprocessed equipment and compromised patient safety.

Recommendations 1–2

1. The Under Secretary for Health requires facility directors ensure that staff who reprocess colonoscopes at community-based outpatient clinics complete initial training within the required 90 days prior to independently reprocessing equipment and maintain documentation.⁴¹
2. The Under Secretary for Health requires facility directors confirm that sterile processing services staff who reprocess colonoscopes at community-based outpatient clinics receive ongoing continuing education through monthly in-services and maintain documentation.

⁴¹ Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge, who had the authority to perform the Under Secretary's functions and duties. Effective January 20, 2021, he was appointed to Acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

Appendix A: Multispecialty CBOCs with Colonoscopy Services

Clinic Name	VISN	Location	Parent Facility Name
Greenville VA Clinic	6	Greenville, NC	Durham VA Medical Center
Wilmington VA Clinic	6	Wilmington, NC	Fayetteville VA Medical Center
William "Bill" Kling VA Outpatient Clinic	8	Sunrise, FL	Bruce W. Carter Department of VA Medical Center
Sergeant Ernest I. "Boots" Thomas VA Clinic	8	Tallahassee, FL	Malcom Randall Department of VA Medical Center
The Villages VA Clinic	8	The Villages, FL	Malcom Randall Department of VA Medical Center
Wyoming VA Clinic	10	Wyoming, MI	Battle Creek VA Medical Center
Pensacola VA Clinic	16	Pensacola, FL	Biloxi VA Medical Center
Austin VA Clinic	17	Austin, TX	Olin E. Teague Veterans' Center
Fort Worth VA Clinic	17	Fort Worth, TX	Dallas VA Medical Center
Redding VA Clinic	21	Redding, CA	Sacramento VA Medical Center

Source: VHA Support Service Center data

Appendix B: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: January 27, 2021

From: Acting Under Secretary for Health (10)

Subj: Colonoscopy Reprocessing at Multispecialty Community-Based Outpatient Clinics

To: Assistant Inspector General for Healthcare Inspections (54)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report Veterans Health Administration: Colonoscopy Reprocessing at Multispecialty Community-Based Outpatient Clinics. The Veterans Health Administration (VHA) concurs with the two recommendations and provide the attached action plan.
2. VHA's National Program Office for Sterile Processing proactively develops and provides ongoing educational opportunities for facility and Community Based Outpatient Clinic staff. These educational offerings ensure the most up to date information on reprocessing colonoscopes and other reusable critical and semi-critical equipment is maintained at the highest level for purposes of patient safety.
3. All VHA Community Based Outpatient Clinics that were reviewed by the OIG team demonstrated compliance with the most up to date colonoscopy information provided by the manufacturers. Step by step instructions for reprocessing colonoscopes were available for Sterile Processing Service staff in decontamination areas where the most critical cleaning steps occur.
4. The National Office of Sterile Processing maintains a robust process in properly checking and evaluating for potential bioburden on endoscopy equipment. This process uses a 100% verification method ensuring each endoscope meets requirements for safe and effective patient care.
5. VHA has strong practices for ensuring high level disinfected endoscopes are stored safely until patient use. Endoscopes are maintained in the most appropriate and safe manner and are traceable from initiation of the disinfection process to the site of care.
6. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Richard A. Stone, M.D.

Acting Under Secretary, Veterans Health Administration

Acting Under Secretary for Health Response

Recommendation 1

The Under Secretary for Health requires facility directors ensure that staff who reprocess colonoscopes at community-based outpatient clinics complete initial training within the required 90 days prior to independently reprocessing equipment and maintain documentation.

Concur.

Target date for completion: June 2021

Acting Under Secretary for Health Comments

VHA concurs that developing a clear and concise process to ensure all new staff, and those staff who began reprocessing of colonoscopes at Community Based Outpatient Clinics after March 23, 2016, have completed and documented the initial training within 90 days prior to independently reprocessing equipment. The National Program Office for Sterile Processing will require Veterans Integrated Service Network SPS Management Boards, who has the responsibility for ensuring reprocessing and other SPS function occur to exacting standards, to substantiate completion. Any non-compliant facilities must develop an action plan for monitoring until compliance is achieved.

Recommendation 2

The Under Secretary for Health requires facility directors confirm that sterile processing service staff who reprocess colonoscopes at community-based outpatient clinics receive continuing education through monthly in-services and maintain documentation.

Concur.

Target date for completion: June 2021

Acting Under Secretary for Health Comments

VHA concurs that all Community Based Outpatient Clinics (CBOC) staff who reprocess colonoscopes will be required to complete monthly in-service training and maintain appropriate documentation to demonstrate compliance. The National Program Office for Sterile Processing will require an attestation, through the Veterans Integrated Service Network Sterile Processing Service (VISN SPS) Management Board. The VISN SPS Management Board has the responsibility to ensure reprocessing and other SPS functions occur to exacting standards, to ensure all CBOC staff who reprocess colonoscopes continue to complete monthly in-services, and to ensure appropriate documentation of this training is maintained, per Directive 1114, with compliance communicated to the National Program Office.

OIG Contact and Staff Acknowledgments

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