US DEPARTMENT OF VETERANS AFFAIRS
**OFFICE OF INSPECTOR GENERAL**

Office of Healthcare Inspections

## VETERANS HEALTH ADMINISTRATION

# Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia

**Healthcare Inspection** | **22-01315-90** | **March 6, 2024**

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# Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess an allegation concerning the improper reprocessing of reusable medical equipment (RME) by the facility's Sterile Processing Service (SPS).[1] The allegation was brought forward to the OIG on January 14, 2022, by a leader from the Carl Vinson VA Medical Center (facility) in Dublin, Georgia. Specifically, it was alleged that an SPS employee did not reprocess an unused endoscope that was potentially exposed to environmental contaminants and instead returned it to sterile storage. Given the unknown extent of this improper practice, including the associated impact on patients; the undetermined length of time the issue existed; and the number of staff involved, the allegation prompted facility leaders to curtail all SPS operations two days earlier involving RME and initiate a large-scale disclosure to over 6,600 veterans at the facility.[2]

In situations with the potential for a large-scale disclosure, the Veterans Health Administration (VHA) requires facilities to coordinate with appropriate Veterans Integrated Service Network (VISN) and VHA partners to develop strategies to communicate with potentially affected patients, and to offer and "provide follow-up treatment and testing when medically indicated based on the clinical circumstances."[3] The decision to make a large-scale disclosure is determined by the risk and benefits "relative to the probability of serious future health consequences." The OIG found that, in response to endoscope reprocessing concerns, the facility consulted the VISN and a national infectious disease subject matter expert, communicated with patients, and instituted testing and follow-up.

VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016, was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. In reviewing the 2023 directive, the OIG did not identify any substantive changes that affect the findings or recommendations in this report.[4]

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[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] *Merriam-Webster.com Dictionary*, "curtailment," accessed March 1, 2023, https://www.merriam-webster.com/dictionary/curtailing. Curtailment of services is when a department (in this case SPS) ceases activities related to processing RME.

[3] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

[4] VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016; This directive was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. Unless otherwise specified, the 2023 directive contains the same or similar language as the rescinded 2016 directive. VHA Directive 1116 removed the requirement to develop a separate standard operating procedure if the manufacturer's instructions for use provides clear guidance to SPS staff about RME.

In VHA facilities, SPS has the primary responsibility for RME.[5] Reprocessing is a term used to describe all of the steps involved in making a contaminated item reusable, including cleaning, testing, and disinfecting or sterilizing.[6] The Centers for Disease Control and Prevention guidelines emphasize that the high-level disinfection or sterilization of RME is essential in preventing the transmission of infectious pathogens to patients. Conversely, failure to properly clean, test, disinfect, or sterilize equipment carries significant risk for person-to-person transmission of infectious diseases.[7]

## Stop the Line, Curtailment, and Standdown Activities

In 2013, VA's Under Secretary for Health introduced the *Stop the Line for Patient Safety* initiative, which empowers "staff to speak up and communicate their concerns to other members of the team regardless of their position" when they encounter a potential patient safety concern. The OIG found that between January and June 2022, the facility had multiple Stop the Line and curtailment events related to SPS reprocessing issues and critical abnormal water test results.

January 12, 2022, at approximately 10:30 a.m., the Associate Director of Patient Care Services (ADPCS) was notified of the SPS endoscope reprocessing issue and an initial Stop the Line occurred. By the end of the day, a second Stop the Line occurred, resulting in all endoscope usage being halted. The following day, to ensure veteran safety, the facility "elected to curtail all surgeries and procedures requiring the use of reusable medical equipment until a thorough investigation could be completed."[8] Facility leaders notified the VISN and the VISN completed an issue brief to VHA as required. In addition, the VISN assembled a team initially from the Charlie Norwood VA Medical Center in Augusta, Georgia, and included the use of detailed staff (SPS staff from outside of Dublin) to perform all SPS duties at the facility until facility SPS staff were retrained and other deficiencies in SPS had been corrected.[9]

On January 28, 2022, facility leaders were notified that an endoscope technician in the operating room was using simethicone during cleaning of endoscopes, which could increase residual bioburden.[10] As a result, a third Stop the Line commenced on January 28, 2022.

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[5] VHA Directive 1116(2); VHA Directive 1116.

[6] VHA Directive 1116(2); VHA Directive 1116.

[7] Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008, updated May 2019, https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

[8] VISN 7 Issue Brief, January 14, 2022; the curtailment of services is when a department (in this case SPS) ceases activities related to processing RME.

[9] A safety standdown is time dedicated to staff for learning, listening, and growing as an organization; psychological safety is a key term related to patient safety and a culture of safety—it is a person's perception of their consequences for reporting. A standdown in this case was the complete stop of SPS employees conducting their day-to-day operations while being retrained and recertified.

[10] The endoscope technician was not an SPS employee.

On April 15, 2022, SPS staff notified facility leaders of potentially harmful, abnormal critical water test results and a second curtailment of operations was initiated resulting in all RME reprocessing being halted once again. The abnormal test results were dated February 28, 2022, and uploaded by the contractor of the water management program to the facility SharePoint site the same day; however, the results were not addressed by facility staff or leaders until April 15, 2022.[11] When the OIG questioned SPS and facility leaders on the reason for the delay in addressing the abnormal critical water test results, they were unable to provide an explanation.

**Table 1. Stop the Line and Curtailment Dates**

| Date | Action Taken | Why It Matters |
|---|---|---|
| January 12, 2022 | • ADPCS notified at 10:30 a.m. of endoscopy reprocessing allegation<br>• First Stop the Line occurs in endoscopy department<br>• Second Stop the Line commenced | • Risk for cross contamination and patient infection<br>• Patient care services delayed in areas that used RME |
| January 13, 2022 | • Curtailment of services for all RME initiated | • Patient care services canceled |
| January 28, 2022 | • Dublin leaders notified that an endoscope technician in the operating room used simethicone during cleaning of endoscopes<br>• Third Stop the Line commenced | • Risk for cross contamination and patient infection<br>• The use of simethicone could increase residual bioburden<br>• Patient care services canceled and delayed in areas that used RME |
| April 15, 2022 | • Dublin leaders were notified of potentially harmful water test results in SPS<br>• Second curtailment of services commenced | • Patient care services canceled and delayed in areas that used RME |
| June 17, 2022 | • Curtailment of SPS services and use of detailed staff (SPS staff from outside of Dublin) ended | |

*Source: VISN 7 Issue Brief, January 14, 2022. VHA Issue Brief, April 15, 2022. Staff interviews and staff correspondence.*

[11] The delayed abnormal water test results were presented to a person serving in an acting leadership position who then called a meeting of the Water Safety Committee.

## Issue 1. Failure of VISN, Facility, and SPS Leaders' to Remediate SPS Deficiencies

The OIG substantiated that an SPS employee placed an unused endoscope back in sterile storage; the item had been potentially exposed to environmental contaminants and required reprocessing, which was not done. Additionally, the OIG identified multiple issues that contributed to the various SPS deficiencies identified in this inspection. These issues included previously identified SPS issues that were not addressed; SPS standard operating procedures (SOPs) that were not updated and not accessible to staff; SPS staff not receiving appropriate training; environment of care (EOC) issues that potentially impacted the integrity of RME; delays in addressing abnormal critical water system test results; and interim and acting leaders negatively impacting SPS culture.[12]

In accordance with VHA Directive 1116(2), the VISN SPS Management Board is charged with the oversight of SPS and reprocessing of critical and semi-critical RME at all VISN facilities. In addition, the VISN SPS Management Board is required to conduct a VISN-led inspection at each facility.[13] After each inspection, the VISN develops recommendations to improve facility processes in SPS. The VISN SPS lead ensures that action plans to address the recommendations are followed to completion. In reviewing the VISN SPS Management Board's meeting minutes, the OIG found no documentation to support that the VISN SPS Management Board complied with the requirement to ensure action plans were followed to completion.

### Failure to Implement CensiTrac

In 2019, a Deputy Under Secretary for Health for Operations and Management memorandum notified staff of the required implementation and use of CensiTrac Instrument Tracking System for SPS.[14] However, the facility failed to utilize the required instrument tracking system as required. During the 2020 OIG comprehensive healthcare inspection at the facility, issues with the implementation of the surgical instrument tracking system, CensiTrac, were identified.[15] Failure to utilize the CensiTrac system was identified again at the 2021 Consultative VISN

[12] The facility uses the terms *interim* and *acting* to refer to staff working in a position on a temporary basis. The OIG chose, for the purposes of this report, to use the term acting.

[13] Deputy Under Secretary for Health for Operations and Management, "Information and Instructions for Fiscal Year 2019 Sterile Processing Services Inspections," memorandum to Network Directors (10N1-23), Chief Medical Officers (1ON 1-23), Quality Management Officers (1ON 1-23), VISN Sterile Processing Service Leads (10N1-23), December 11, 2018.

[14] VHA Deputy Under Secretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services," memorandum to the Veterans Integrated Service Network Directors, January 1, 2019. "The CensiTrac® Instrument Tracking System (ITS) [ ] is the defacto standard ITS that all facilities shall utilize."

[15] VA OIG, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 20-00130-06, November 12, 2020; CensiTrac is an electronic tracking program that, when used correctly, tracks instruments from the beginning of reprocessing, through transporting, storing, and use.

inspection. At the time of the March 2022 OIG site visit, CensiTrac was still not being utilized throughout SPS.

At the time of the OIG's on-site review in March 2022, the OIG learned during interviews that despite being hired in 2020, the CensiTrac coordinator had not been trained in the CensiTrac Instrument Tracking System process. The CensiTrac coordinator cited the COVID pandemic as the reason training was not provided.[16]

## Failure to Control Traffic Flow in Sterile Areas

The VISN SPS consultative visit on August 27, 2021, led by the SPS VISN lead, reported that the facility failed to control traffic flow in the sterile storage area as required. They found that contrary to VHA policy, staff were eating, drinking, or storing food in sterile storage areas.[17] Traffic flow must be controlled in these areas to minimize contamination of the environment due to microorganisms present on human bodies and clothing. The OIG confirmed, during a site visit in March 2022, that this issue had not been resolved. According to an OIG interview with the facility chief engineer, the options to bring the facility into compliance with VHA requirements were expensive (remodel) or inconvenient (would preclude staff from using the training room as a lunchroom).

## SPS SOP's Were Not Updated and Not Accessible to Staff

During the OIG's unannounced inspection of clinics where the SPS processes of decontamination, sterilization, or clean and sterile storage were performed, OIG team members observed that the SPS SOPs were not updated as required. In addition, end-user staff were not always able to identify the location of SPS SOPs within their work area.

VHA Directive 1116(2) requires the development and dissemination of reprocessing SOPs and competency assessments for all critical and semi-critical RME according to manufacturer's instructions for use (IFU). In addition, SOPs must be reviewed at least once every three years, updated when there is a change in process or a change in manufacturer's IFU, and consistently accessible to all staff at all times.

Prior to January 2022, the development and updating of the SPS SOPs was the responsibility of the RME coordinator, with the acting chief of SPS and ADPCS's review and signature. The facility RME coordinator, a nurse with no prior SPS experience, entered on duty in March 2020.

[16] "COVID-19 (coronavirus disease 2019) is a disease caused by a virus named SARS-CoV-2…COVID-19 most often causes respiratory symptoms that can feel much like a cold, the flu, or pneumonia. COVID-19 may attack more than your lungs and respiratory system. Other parts of your body may also be affected by the disease. Most people with COVID-19 have mild symptoms, but some people become severely ill." CDC, *About COVID-19,* accessed February 28, 2024, About COVID-19 | CDC.
[17] VHA Directive 1116(2); VHA Directive 1116.

While the RME coordinator is still responsible for the development and updating of the SOPs, SPS SOPs are also vetted and voted on at the RME monthly meetings.

The failure to ensure that current and accessible SPS SOPs were available facility-wide was also identified in a 2019 National Program Office of Sterile Processing review, 2020 OIG review, and a 2021 VISN-led SPS consultative visit. The OIG concluded that unstable or vacant leadership positions in SPS and the failure of facility leaders to provide resources, support, or training contributed to the RME coordinator's inability to successfully resolve this issue.

## SPS Staff Did Not Receive Appropriate Training

The OIG determined that significant training and competency failures existed in SPS. Despite the requirements outlined in the 2018 Deputy Under Secretary for Health for Operations and Management memorandum (2018 Memo), instructing all facilities to identify RME champions to serve as the point of contact for RME end-users and clinical staff, RME champions had not been identified nor received training until February 2022.[18] Further, the OIG determined during interviews with SPS staff and the medical supply technician trainer that individuals responsible for SPS training and competencies were ineffective, and staff responsible for RME reprocessing were not fully attentive or engaged in the training. The OIG concluded that unstable leadership positions in SPS, and the failure of facility leaders to provide resources or support, contributed to inadequate training of SPS employees, which resulted in competency failures.

## Abnormal Critical Water System Test Results Were Not Addressed Timely

On April 15, 2022, staff informed the acting Associate Director of abnormal critical water system test results. The abnormal test results, dated February 16, 2022, were available to the facility liaison on February 28, 2022. Although the results had been available, they were not accessed by the ADPCS or SPS leaders, or acknowledged by the Water Working Group, until April 2022.[19] After learning of the February 2022 abnormal critical water system test results, the acting Associate Director called an emergency Water Working Group meeting the same day and the decision was made to curtail services and retest the SPS critical water system.

[18] VHA Deputy Under Secretary for Health for Operations and Management, "Clarification of Reusable Medical Equipment Committee Oversight and Membership Requirements;" memorandum to Network Directors, Chief Medical Officers, Quality Management Officers, and VISN Nurse Sterile Processing Boards, January 23, 2018. "RME Champions identified within each service line will serve as a "go-to" point of contact for facility staff when addressing RME matters specific to the service line. The purpose of the Champion is to ensure the appropriate handling of RME in clinical areas and share technical knowledge from the clinician's perspective as an active/ad hoc member of the RME Committee."

[19] The Water Working Group is a multidisciplinary group responsible for continuous assessment and reporting of water quality as it relates to biocide levels, temperature, cleaning, and taking action to notify facility leaders of water results.

The OIG found that the facility liaison, a facility staff member who is responsible for communicating information between the contractor of the water management program and the facility, failed to effectively communicate the contractor's notification of abnormal critical water system testing results to the facility Water Working Group and facility leaders.

In addition, the OIG found, during review of the documentation received from the facility and the water management program contractor, that SPS had consistently abnormal critical water system test results for approximately two years that dated back to September 2020.

The OIG also found that SPS did not consult with VA Office of Healthcare Engineering upon learning of consistently out of range results. Although not required by policy, this is VHA's standard practice for determining remediation options.

### Interim and Acting Leaders Negatively Impacted SPS Culture

Over the past several years, both the SPS chief and assistant chief positions were temporarily filled with interim or acting roles. The OIG found that the series of acting or short-term staff in the SPS chief and assistant chief positions contributed to the system's failure to focus on the monitoring and management of SPS challenges. At the time of the OIG's inspection, interviews for the SPS chief position were being conducted. A permanent assistant chief was scheduled to start June 19, 2022, and the permanent chief entered on duty on July 5, 2022.

The OIG also found the culture within SPS did not consistently support a commitment to teamwork and the pursuit of achieving SPS's mission. The collective elements of facility culture affect the efficiency and timeliness of day-to-day work. The OIG reviewed administrative investigations board transcripts and external reviews and discussed with SPS staff how they perceived the overall culture in the SPS department. Multiple staff members reported a culture of intra-departmental conflict, a difficult work environment, and racial divide.

## Issue 2. EOC Concerns

The OIG completed physical inspections of, and interviewed staff within, the following areas in the facility where SPS RME equipment is reprocessed or used: SPS; dental, radiology, podiatry, and optometry; operating room; and endoscopy; as well as the corresponding sterile storage areas. The proper storage of clean and sterile supplies is essential in preventing contamination and patient infections, as well as product deterioration. To maintain supplies properly, clean and sterile storage rooms must have stable temperature and humidity, and restricted access. Table 2 includes the EOC-related deficiencies identified.

**Table 2. EOC Concerns**

| EOC Location | Concern | Why It Matters |
|---|---|---|
| Dental clinic | • Inconsistent compliance with negative/positive pressure, ventilation, temperature, and humidity requirements for clean/sterile and soiled utility room | • Risk for contamination<br>• VHA requirement |
| Operating room | • No designated soiled utility room to rinse or clean soiled instruments and did not have a dedicated sink for handwashing after handling soiled instruments | • Risk for cross contamination and infection control<br>• VHA requirement |
| Radiology department | • No SPS cart to place soiled vaginal probes and soiled probes placed on clean linen cart in patient care area | • Risk for cross contamination<br>• VHA requirement |
| Optometry, Podiatry, Urology, and Primary Care departments | • Clean and sterile storage room contained both clean and dirty equipment | • Risk for cross contamination<br>• VHA requirement |
| Endoscopy clinic Decontamination area | • SPS staff did not follow personal protective equipment (PPE) requirements in the decontamination area | • Risk for cross contamination<br>• VHA requirement |

*Source: OIG EOC round observations at CVVAMC March 2022. VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016; VHA Directive 1116, Management of Critical and Semi-Critical Reusable Medical Devices, July 17, 2023.*
*Note: Throughout this table, any reference to "VHA requirement" refers to VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016; VHA Directive 1116, Management of Critical and Semi-Critical Reusable Medical Devices, July 17, 2023.*

The OIG determined that facility leaders were aware of EOC issues, outlined above in Table 2, that had been identified in prior inspections conducted by the National Program Office of Sterile Processing, VISN, and OIG. The long-standing SPS-related EOC issues suggest that the cultural issues extended beyond those identified in SPS.[20]

Finally, compounding the lack of accountability by facility staff was the VISN's lack of oversight. An inspection was conducted by the VISN 7 SPS lead and recommendations were made, but there was no oversight to ensure the recommendations were followed to completion.

[20] The OIG, in its oversight role, does not review personnel actions; as such, no recommendations were made in this report related to the personnel issues raised during this inspection.

## Recommendations

The OIG made two recommendations to the VISN Director related to reviewing the facility's SPS water management program and ensuring compliance with VHA guidance; and ensuring the VISN SPS Management Board reviews the results of critical water test results submitted by the facility Water Working Group, and takes corrective action as appropriate.

The OIG made seven recommendations to the Facility Director related to ensuring that the SPS chief conducts comprehensive staff competency assessments for the reprocessing of RME; the CensiTrac Instrument Tracking System is fully implemented, and training is provided to the CensiTrac coordinator and SPS staff; SPS staff maintain a safe and clean environment in all areas where decontamination, sterilization, or clean and sterile storage of RME are performed; an action plan is developed for remediation of the location and use of the training room adjacent to SPS's clean and sterile storage area; clinic areas, including radiology, have or share a designated soiled utility room as required by VHA policy; the development and dissemination of reprocessing SOPs for all critical and semi-critical RME according to manufacturer's IFU are developed; and the facility Water Working Group submits critical water test results to the VISN SPS Management Board.

## VA Comments and OIG Response

The Veterans Integrated Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

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# Contents

# Abbreviations

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|---|---|
| ADPCS | Associate Director of Patient Care Services |
| AIB | Administrative Investigations Board |
| CERT | Clinical Episode Review Team |
| EOC | environment of care |
| HRO | high reliability organization |
| IFU | instructions for use |
| MST | medical supply technician |
| NPOSP | National Program Office of Sterile Processing |
| OIG | Office of Inspector General |
| PPE | personal protective equipment |
| RME | reusable medical equipment |
| SOP | standard operating procedure |
| SPS | Sterile Processing Service |
| VHA | Veterans Health Administration |
| VISN | Veterans Integrated Service Network |

# Introduction

On January 14, 2022, a facility leader from the Carl Vinson VA Medical Center (facility) in Dublin, Georgia, notified the Office of Inspector General (OIG) of concerns with the reprocessing of reusable medical equipment (RME) by the facility's Sterile Processing Service (SPS).[1] SPS employees, during interviews with a facility leader, alleged that an SPS employee placed an unused endoscope back in sterile storage; the item had been potentially exposed to environmental contaminants and required reprocessing, which was not done. In response to the allegation, the facility curtailed all SPS operations. Due to the unknown extent of this improper practice, a large-scale disclosure was initiated.

The facility has a history of unstable SPS leadership and failure to resolve SPS deficiencies cited during prior inspections conducted by the National Program Office of Sterile Processing (NPOSP), Veterans Integrated Service Network (VISN), and OIG. The failure to remediate identified findings over time contributed to the resulting large-scale disclosure to over 6,600 veterans that was potentially preventable.[2]

The purpose of this review was to outline the initial sequence of events related to the endoscope concern; review additional concerns brought forth during this inspection regarding SPS processes such as critical water system test results and reprocessing of RME, and leaders' response to the identified deficiencies; and to evaluate the factors that may have contributed to the SPS failures. The OIG also reviewed the facility's environment of care (EOC) with respect to SPS areas and activities.

## Background

The facility has six community-based outpatient clinics located in Albany, Brunswick, Macon, Milledgeville, Perry, and Tifton, Georgia. The Veterans Health Administration (VHA) classifies the facility as level 2 complexity.[3] The facility provides acute medical and surgical services, outpatient and specialty care services, and mental health and long-term care services. At the time of the review, the facility provided services across 49 counties in Georgia and treated more than 41,000 veterans with over 455,000 visits annually. The facility is part of VISN 7.

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[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together; the facility senior leader initially contacted the OIG's Office of Investigations who determined that the concerns did not meet their criteria of criminal activity and forwarded the information to the OIG's Office of Healthcare Inspections.

[2] The OIG did not independently verify VHA data for accuracy or completeness.

[3] VHA Office of Productivity, Efficiency, and Staffing (OPES), "Facility Complexity Model Fact Sheet," January 28, 2021, accessed April 13, 2023. "The model rates facilities as 1a, 1b, 1c, 2 or 3, with facilities rating 1a being the most complex and those rated 3 the least complex." A level 2 medium complexity facility has "medium volume, low risk patients, few complex clinical programs, and small or no research and teaching programs."

## SPS

In VHA facilities, SPS has the primary responsibility for RME.[4] Reprocessing is a term used to describe all of the steps involved in making a contaminated item reusable, including cleaning, testing, and disinfecting or sterilizing.[5] The Centers for Disease Control and Prevention guidelines emphasize that the high-level disinfection or sterilization of RME is essential in preventing the transmission of infectious pathogens to patients. Conversely, failure to properly clean, test, disinfect, or sterilize equipment carries significant risk for person-to-person transmission of infectious diseases.[6]

For each piece of RME, which includes items such as endoscopes, surgical, and dental instruments, a medical facility is responsible for developing standard operating procedures (SOPs) for reprocessing according to the biomedical equipment manufacturer's instructions for use (IFU). As such, personnel responsible for RME must be trained according to IFU device-specific generated SOPs for reprocessing RME. Competencies must be established and demonstrated for the proper reprocessing procedure for each item. Continuous quality education and supervision of SPS staff, reevaluation, and remediation of deficiencies within the SPS program are paramount to ensuring the lowest possible risk of infection to patients.[7] A breach in the established process or being less meticulous in those steps has the potential to harm patients by not clearing pathogens such as human immunodeficiency virus, hepatitis B, hepatitis C, or other viruses and bacteria that could cause infection.

## Large-Scale Disclosure

"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 have been or may have been affected by an adverse event involving actual or potential harm to multiple patients." A large-scale disclosure may, when medically indicated, entail an offer by the facility to provide follow-up treatment and testing.[8]

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[4] VHA Directive 1116(2), *Sterile Processing Services (SPS),* March 23, 2016; This directive was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. Unless otherwise specified, the 2023 directive contains the same or similar language as the rescinded 2016 directive. VHA Directive 1116 removed the requirement to develop a separate standard operating procedure if the manufacturer's instructions for use provides clear guidance to SPS staff about RME.

[5] VHA Directive 1116(2); VHA Directive 1116.

[6] Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008, updated May 2019, https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

[7] VHA Directive 1116(2); VHA Directive 1116.

[8] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

## Prior OIG Reports

In November 2020, the OIG published a report, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*. The OIG identified deficiencies in SPS with administrative processes, quality assurance monitoring, reprocessing, storage area physical inspections, and staff training. Additionally, the OIG found the facility did not maintain a current inventory file for RME, which may have resulted in the potential loss of reusable devices. The OIG made 17 recommendations to facility leaders, with 8 pertaining to SPS; all SPS-related recommendations have been closed.[9]

## Areas of Concern

According to a February 2022 VHA memorandum, the facility conducted an administrative investigations board (AIB) related to SPS allegations of acts of fraud, waste, abuse, or sabotage.[10] During the AIB, two SPS interviewees raised another concern, alleging that an SPS staff member placed an unused endoscope back in sterile storage after a patient did not show up for the procedure on January 4, 2022. According to the Associate Director of Patient Care Services (ADPCS), the item had been potentially exposed to environmental contaminants and required reprocessing, which was not done. The Facility Director told the OIG that given the unknown scope of this improper practice, including the associated impact on patients and undetermined length of time the issue existed, the allegation prompted facility leaders to curtail all operations involving RME. According to interviews, the allegation also compelled the VISN leaders to conduct an investigation and take over reprocessing activities until facility staff were retrained and other deficiencies had been corrected. Further, because the alleged event on January 4, 2022, established the basis for a potential large-scale disclosure, VHA's central office-level Clinical Episode Review Team (CERT) became involved and consulted with staff at the facility on January 24th.[11]

The purpose of the OIG's inspection was to

- outline the sequence of events and how facility, VISN, and VHA leaders responded to the allegation brought forward during the AIB;
- evaluate the factors that may have contributed to the SPS failures; and
- assess compliance with select EOC requirements for those areas where cleaning, handling, reprocessing, and storing of RME occurs.

[9] VA OIG, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 20-00130-06, November 12, 2020.

[10] The AIB was completed on February 24, 2022.

[11] VHA Directive 1004.08. "The Clinical Episode Review Team (CERT) is the name of the team that serves as the Deputy Under Secretary for Health for Operations and Management's coordinated triage process for review of each potential adverse event that may require large-scale disclosure."

In mid-April 2022, the OIG was informed by the acting Associate Director of another curtailment of operations due to abnormal critical water test results that were obtained in February of 2022 within SPS and where SPS services are provided. However, neither facility leaders nor SPS leaders reviewed those results until April 2022. Therefore, in April 2022, the facility had to cancel procedures, reschedule appointments, retest, and initiate remediation of the critical water system. Also, in April, the OIG began an in-depth review of the water management program at the facility to include a review of the contractor of the water management program.[12] After a review of critical water test results, the OIG learned that the critical water test results were abnormal from September 2020 to June of 2022. The OIG found no evidence of associated remediation actions as a result of these water test results.

# Scope and Methodology

The OIG initiated the inspection on January 20, 2022, and conducted an unannounced site visit March 1–3, 2022. The OIG conducted interviews January 31–June 14, 2022.

The OIG interviewed VISN leaders and staff, facility leaders, and other staff knowledgeable about the issues under review. In addition, the OIG interviewed VHA subject matter experts from the NPOSP, CERT team, and the VA Office of Healthcare Engineering. The OIG also interviewed staff from the contracted water management program (contractor).

The OIG reviewed relevant Joint Commission Standards; VHA directives; facility policies, SOPs, IFUs, SPS meeting minutes and recordings, and SPS training and competency records; and the VISN water management program contract (contract). Additionally, the OIG team reviewed facility patient safety event reports related to SPS or RME from October 2020 through April 2022; facility processing logs for endoscopic equipment from January 2022; and SPS-related reviews conducted by the NPOSP, VISN, and OIG from March 2019 to March 2022.

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). VHA Directive 1116(2), *Sterile Processing Services (SPS),* March 23, 2016, was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. In reviewing the 2023 directive, the OIG did not identify any substantive changes that affect the findings or recommendations in this report.[13]

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General (IG) Act of 1978, as amended, 5 U.S.C. §§ 401-424. The OIG reviews

[12] The statement of work from the contractor defines the water management program to include "all necessary labor, materials, and equipment necessary to provide Water Management Program Operations, Validation Testing, Continuous Water Monitoring, and Web-based Data Management."

[13] VHA Directive 1116(2); VHA Directive 1116.

available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

# Sequence of Events and Leaders' Response

Based on interviews and information provided by facility staff, a consolidated timeline of events related to the allegations of suboptimal reprocessing practices, as well as actions taken by leaders to remediate these concerns, follows. Although the facility's response to the allegations was satisfactory, the inaction and failure to remediate identified SPS concerns over time, which ultimately led to the allegations, indicated a lack of accountability from SPS and facility leaders.

According to the ADPCS, in May 2021, allegations relating to a hostile work environment came to light. After the notification, the ADPCS conducted a listening session with SPS staff where allegations were made of potential fraud, waste, and abuse, among other concerns. In June, SPS staff participated in a variety of activities, including diversity, team building, safety standdown, and psychological safety trainings, but concerns related to SPS team behavior and incivility persisted.[14] In July, the executive assistant to the ADPCS conducted a listening session at the request of the acting chief nurse of SPS for SPS staff to voice their concerns. The concerns raised prompted a formal fact-finding review, concluded in November, which resulted in a recommendation to conduct an AIB.[15] On December 14, the acting Facility Director chartered an AIB to investigate "the facts and circumstances regarding allegations of acts of fraud, waste, or abuse. . ." and "acts of sabotage, or any other activities intended to cause delay in operations."

The ADPCS reported that on January 10, 2022, the facility commenced the AIB. Two days later, during interviews conducted as part of the AIB, two SPS employees reported that on January 4, 2022, an endoscope was not reprocessed as required and provided pictures and text messages to support this claim. After learning of the January 4 event, facility leaders initiated several actions to address suboptimal reprocessing practices and to mitigate the potential for future harm,

[14] A safety standdown is time dedicated to staff for learning, listening, and growing as an organization; psychological safety is a key term related to patient safety and a culture of safety—it is a person's perception of their consequences for reporting. A standdown in this case was the complete stop of SPS employees conducting their day-to-day operations while being retrained and recertified.

[15] At the time of the OIG's review, the AIB was not complete; however, the OIG did not focus on the same concerns that the AIB reviewed. Rather, the OIG reviewed the concerns that led up to the chartering of the AIB and leaders' response to the concerns.

including the issuance of a large-scale disclosure. Select actions taken by the facility, as well as by the responsible leaders, are summarized below.

## Notifications

VHA requires that potential large-scale disclosures be coordinated with VA Central Office for the assessment and planning process. "To initiate this coordination process, the VA medical facility Director, VISN Director, or program officer, as appropriate, must submit an Issue Brief within 24 hours of discovery of the event."[16]

After becoming aware of the SPS concerns, facility leaders immediately notified VISN 7. The VISN completed an issue brief, as required, which prompted involvement of the VISN 7 Tiger Team, a national infectious disease subject matter expert, the NPOSP, and the CERT to assist with a large-scale disclosure to over 6,600 veterans.[17] The issue brief has been updated several times, providing the status of issues and actions through March 1, 2022.[18] In addition, on January 14, 2022, an acting facility leader notified the OIG, Office of Investigations, of the allegations that employees were not sterilizing equipment, which resulted in the halting of all surgical procedures that used RME. The Office of Investigations notified the Office of Healthcare Inspections about the acting facility leader's allegations because they included patient safety and quality of care concerns.

## Stop the Line, Curtailment, and Standdown Activities

In 2013, VA's Under Secretary for Health introduced the *Stop the Line for Patient Safety* initiative, which empowers "staff to speak up and communicate their concerns to other members of the team regardless of their position" when they encounter a potential patient safety concern. The initiative identifies three steps: "Say What You See," "Say what you are concerned about," and "Say what you want to happen to keep things safe." On January 12, 2022, the ADPCS reported being notified of the SPS endoscope issue, and an initial Stop the Line occurred. By the end of the day, a second Stop the Line occurred, resulting in all endoscope usage being halted. On January 13th, to ensure veteran safety, the facility "elected to curtail all surgeries and

[16] VHA Directive 1004.08; VHA Deputy Under Secretary for Health for Operations and Management (10N), "10N Guide to VHA Issue Briefs," June 26, 2017. Issue briefs provide facility, VISN, and VHA leaders clear, concise, and accurate information about a situation or an event.

[17] "Tiger Teams are cross-functional teams pulled together for a period of time to address a critical issue." https://tech.gsa.gov/guides/tiger_teams/, accessed May 11, 2022.

[18] VHA Directive 1004.08.

procedures requiring the use of reusable medical equipment until a thorough investigation could be completed."[19]

In addition, the ADPCS further reported a safety standdown for all facility SPS staff began on January 12, 2022. SPS operations resumed January 19 at the facility with a team from the Charlie Norwood VA Medical Center in Augusta, Georgia, performing all SPS duties.[20] Facility SPS staff were in standdown status starting January 12 and remained in standdown until June 17, 2022, according to electronic correspondence the OIG received from the chief of quality, safety, and value with information provided by the acting chief of SPS. During that time, SPS staff received clinical team training, High Reliability Organization Baseline training, and Joint Patient Safety Report training. Facility SPS staff also repeated Level 1 certification training and classroom training specific to instrumentation, preparation, and decontamination.[21] The ADPCS told the OIG simulation training occurred the last week of January 2022.

On January 28, 2022, the ADPCS reported being notified by the VISN 7 Tiger Team lead that an endoscope technician in the operating room was using simethicone during cleaning of endoscopes, which could increase residual bioburden, and as a result, a third Stop the Line commenced.[22] The following week, an NPOSP representative was on-site to provide consultation. Facility SPS staff remained on standdown, with the VISN 7 Tiger Team and the Charlie Norwood VA Medical Center team providing hands-on training. The ADPCS further stated Charlie Norwood VA Medical Center remained in charge of facility SPS operations.

At the time of the OIG's on-site visit March 1–3, 2022, facility SPS staff had received updated training and passed their competencies in reprocessing endoscopes. Two facility medical supply technicians (MSTs) were reprocessing endoscopes in the endoscopy suite. In addition, two other facility MSTs worked with SPS staff detailed from other facilities.[23]

On April 15, 2022, according to an issue brief, SPS staff notified facility leaders of potentially harmful, abnormal critical water test results, and a curtailment of operations was initiated, resulting in all RME reprocessing being halted. The facility liaison, a facility staff member who is responsible for communicating information between the contractor of the water management

[19] *Merriam-Webster.com Dictionary*, "curtailment," accessed March 1, 2023, https://www.merriam-webster.com/dictionary/curtailing. The curtailment of services is when a department (in this case SPS) ceases activities related to processing RME; VISN 7 Issue Brief, January 14, 2022.

[20] *Stop the Line* is an initiative that encourages employees to speak up and report any behaviors, actions, or inactions that could lead to error or patient harm. The initiative protects employees from retribution when they report concerns to supervisors, team members, and VHA leaders.

[21] VHA Directive 1116(2); VHA Directive 1116. VHA Level 1 Training is related to procedures for the decontamination, disinfection, and sterilization of RME; the training is required within 90 days of hire and employees receive a certificate when the modules are successfully completed.

[22] According to electronic correspondence by the chief of quality management, the endoscope technician was a surgery technician and not an SPS employee.

[23] One SPS volunteer was from Montana, and another was from Georgia.

program and the facility, reported to the OIG that the abnormal test results were dated February 28, 2022, and were made available by the contractor of the water management program on the contractor's web-based system. That same day, the facility liaison also reported, retrieving and uploading the test results to the facility's internal web portal; however, according to an interview with the acting Facility Director for the day, the results were not addressed by facility staff or leaders until April 15, 2022.[24] When the OIG questioned SPS and facility leaders on the reason for the delay in addressing the abnormal critical water test results, they were unable to provide an explanation. This is an example of SPS and facility leaders' disengagement from oversight responsibilities.

The OIG received electronic correspondence with notification that the curtailment of services and the use of detailed staff ended on June 17, 2022. Stop the Line and curtailment dates are displayed in Table 1.

**Table 1. Stop the Line and Curtailment Dates**

| Date | Action Taken | Why It Matters |
|---|---|---|
| January 12, 2022 | • ADPCS notified at 10:30 a.m. of endoscopy reprocessing allegation<br>• First Stop the Line occurs in endoscopy department<br>• Second Stop the Line commences | • Risk for cross contamination and patient infection<br>• Patient care services delayed in areas that used RME |
| January 13, 2022 | • Curtailment of services for all RME initiated | • Patient care services canceled |
| January 28, 2022 | • Dublin leaders notified that an endoscope technician in the operating room used simethicone during cleaning of endoscopes<br>• Third Stop the Line commenced | • Risk for cross contamination and patient infection<br>• The use of simethicone could increase residual bioburden<br>• Patient care services canceled and delayed in areas that used RME |
| April 15, 2022 | • Dublin leaders were notified of potentially harmful water test results in SPS<br>• Second curtailment of services commenced | • Patient care services canceled and delayed in areas that used RME |
| June 17, 2022 | • Curtailment of SPS services and use of detailed staff (SPS staff from outside of Dublin) ended | |

[24] The delayed abnormal critical water test results were presented to a person serving in an acting leadership position who then called a meeting of the Water Safety Group.

*Source: VISN 7 Issue Brief, January 14, 2022; VHA Issue Brief, April 15, 2022; staff interviews; and staff correspondence.*

## Rescheduling of Canceled Procedures

VHA requires the rescheduling of procedures and appointments canceled by the facility clinic.[25] According to the VISN issue brief related to the endoscope reprocessing concern that occurred on January 4, 2022, SPS services were suspended, in whole or in part, on January 13, 14, 18, 19, and 28. The suspensions resulted in 150 appointments for procedures in surgery, endoscopy, dental, urology, and podiatry being canceled. As of January 28, 2022, all 150 canceled appointments were being addressed; 36 were referred to care in the community, 105 were rescheduled, and 9 were pending rescheduling.[26]

As a result of the abnormal critical water test results from February 28, 2022, there was a curtailment of operations in endoscopy, urology, and general surgery on April 15. According to information received from the facility, 171 procedures were canceled and rescheduled; 10 consults were referred to care in the community.

## Steps to Manage Large-Scale Disclosure

In situations with the potential for a large-scale disclosure, VHA requires facilities to coordinate with appropriate VISN and VHA partners to develop strategies to communicate with potentially affected patients, "an offer to provide follow-up treatment and testing when it is medically indicated based on the clinical circumstances." The decision to make a large-scale disclosure is determined by the risk and benefits, "relative to the probability of serious future health consequences." The OIG found during interviews that, in response to the endoscope reprocessing concerns, the facility consulted a national infectious disease subject matter expert. According to the issue brief, the expert assisted in determining patients to include in the disclosure.[27]

The facility had identified over 6,600 patients potentially affected by deficient RME reprocessing practices. Based on discussions held with a national infectious disease subject matter expert and the CERT, the facility selected a lookback period of January 1, 2021, through January 28, 2022. In an interview with OIG, the director of CERT explained that the criteria used when determining which patients might have been exposed was very broad and they had to operate on clinical fact. The lookback included endoscopy, urology, dental, podiatry, and surgery patients. They could not tell with 100 percent certainty that the endoscopic processes were being conducted correctly across fields. Due to endoscopes being complex and delicate instruments with various holes and ports, thorough and orderly sterilization through many steps is required to

[25] VHA Directive 1230 (1), *Outpatient Scheduling Processes and Procedures*, July 15, 2016, amended July 12, 2019.

[26] VHA provided the total number of appointments; the OIG did not validate the data provided.

[27] VHA Directive 1004.08.

ensure the elimination of contaminants. A breach in this multi-step process or being less meticulous in those steps has the potential to harm patients by not clearing out pathogens such as human immunodeficiency virus, hepatitis B, hepatitis C, other viruses, or bacteria and causing infection. The OIG was also informed, a letter was sent to each identified patient providing contact information for anyone interested in obtaining testing for human immunodeficiency virus, hepatitis B, and hepatitis C. When an interested patient contacted the facility, a registered nurse entered the testing order and the primary care physician was responsible for the results. The individual patient's primary care team was responsible for notifying the patient of the results.

In March of 2022, the chief of primary care told the OIG that primary care physicians will continue to evaluate patients' viral load and the need for follow-up care for an undetermined length of time.[28] However, linking a patient's infection with an RME exposure may be difficult. As of March 2022, 138 patients had received positive test results. The OIG determined that the actions taken by facility leaders in response to the endoscope reprocessing failures were appropriate; however, this concern, with the associated potential serious health consequences for patients, could have possibly been avoided if leaders had remediated reprocessing failures and other SPS deficiencies when first identified.

# Inspection Results

The OIG substantiated that an SPS employee placed an unused endoscope back in sterile storage; the item had been potentially exposed to environmental contaminants and required reprocessing, which was not done. While the OIG determined that facility and VISN leaders took appropriate and timely actions *after* learning of the endoscope issue on January 4, 2022, the OIG found that VISN, facility, and SPS leaders had enabled a culture of complacency and unaccountability due to their failure to address deficient conditions that ultimately resulted in increased patient safety issues within SPS. Many of the deficient conditions discussed in this report were cited in previous external reviews occurring between 2019–2021, but corrective actions were either not taken or were slow to take shape. Further, several of the conditions were conspicuous and should have been identified by responsible employees with an understanding of RME-related guidance. The failure of facility leaders to address deficient conditions when they were initially identified, coupled with a weak SPS safety culture and noncompliant operational processes, repeatedly placed patients at risk for poor clinical outcomes and "set the stage" for the large-scale disclosure in this case. The OIG also identified through a review of documentation provided by the chief of

[28] *Merriam-Webster.com Dictionary*, "viral load," accessed August 1, 2022, https://www.merriam-webster.com/dictionary/viral%20load. The viral load is the amount of a deleterious or pathogenic agent, growth, or substance present in a human or animal body or test sample (as of blood or tissue).

quality, safety, and value that the facility has a history of unstable leadership, which may have contributed to the lack of accountability and the failure to address complacency among staff.[29]

## Issue 1. Failure of VISN, Facility, and SPS Leaders to Remediate SPS Deficiencies

The OIG identified multiple issues that contributed to the various SPS deficiencies during this inspection. These issues included previously identified SPS issues that were not addressed; SPS SOPs that were not updated and not accessible to staff; SPS staff did not receive appropriate training; delays in addressing abnormal critical water system test results; and interim and acting leaders negatively impacting SPS culture.[30]

Issues with the implementation of CensiTrac Instrument Tracking System, failure to control traffic flow in sterile storage areas, and a lack of availability of current SOPs were repeatedly identified by the VISN, as well as other oversight entities. For example, the VISN identified in a consultative visit report dated August 27, 2021, that the facility failed to control traffic flow in sterile storage areas. They found that contrary to VHA policy, staff were eating, drinking, or storing food in sterile storage areas. The deficiencies, however, remained unaddressed and the facility's failure to comply with VHA requirements was ignored by VISN leaders. As a result, patient safety was potentially compromised.

According to VHA, the VISN Director is responsible for "appointing and maintaining a VISN SPS Management Board." The VISN SPS Management Board is charged with oversight of SPS, as well as the "reprocessing of critical and semi-critical RME," at all VISN facilities.[31] The VISN is responsible for one VISN-led inspection at each VISN facility, and at minimum, the team must include the VISN SPS lead. After each inspection, the VISN SPS lead provides results to the VISN SPS Management Board and develops action plans to improve facility processes. The VISN SPS lead ensures that action plans are followed to completion.[32]

In reviewing the VISN SPS Management Board's meeting minutes, the OIG found no documentation that the VISN SPS Management Board complied with the requirement to ensure action plans and outcomes were met. At each facility, the operational responsibility for SPS

[29] The facility's permanent Director was appointed on January 18, 2022; from June 2021 through January 17, 2022, there were multiple acting directors. In addition, there have been several acting associate directors since September 2021. The Chief of Staff and ADPCS have been in their roles for more than two years.

[30] The facility uses the terms *interim* and *acting* to refer to staff working in a position on a temporary basis. The OIG chose, for the purposes of this report, to use the term acting.

[31] VHA Directive 1116(2); VHA Directive 1116.

[32] Deputy Under Secretary for Health for Operations and Management, "Information and Instructions for Fiscal Year 2019 Sterile Processing Services Inspections," memorandum to Network Directors (10N1-23), Chief Medical Officers (1ON 1-23), Quality Management Officers ( 1 ON 1-23), VISN Sterile Processing Service Leads (10N1-23), December 11, 2018.

activities and areas largely falls to the chief of SPS, with oversight responsibility assigned to the ADPCS. The OIG found that the acting chief of SPS did not respond proactively to identified SPS failures that resulted in episodes of curtailment of reprocessing RME, interruption in access to patient care at the facility while deficiencies were addressed, a large-scale disclosure, and other potential patient safety issues.

In a high reliability organization (HRO) with a Just Culture, anyone with concerns that could affect patient safety are encouraged to speak up.[33] VHA adopted the HRO framework that requires leaders at all levels to commit to continuously improving safety using a network of empowered teams. A specific characteristic of a HRO is sensitivity to operations. In this framework, leaders and staff understand the implications of their day-to-day work or environment and how it impacts the delivery of care for patients. The OIG found during SPS staff interviews and document reviews that SPS and facility leaders did not adopt the HRO characteristics of a Just Culture. An example of the lack of a Just Culture, as reported by staff during interviews, was the failure of SPS staff to report the endoscopy reprocessing issue timely as they feared possible retaliation. In addition, multiple SPS staff provided conflicting statements about what had happened and who was responsible for the alleged actions on January 4, 2022; therefore, the OIG was unable to determine the accuracy of the allegations.

## Failure to Implement CensiTrac

VHA requires facilities to use CensiTrac, which improves patient safety and helps achieve sustainable processes while also providing a means for auditing and quality improvement. CensiTrac is an electronic tracking program that, when used correctly, tracks instruments from the beginning of reprocessing, through transporting, storing, and use.[34] Furthermore, using CensiTrac ensures facilities have an accurate up-to date-electronic master list of all RME. The master list can then be used to ensure all staff are trained and proficient on all current and newly implemented RME prior to use, as required by VHA.[35]

The CensiTrac coordinator had been in the position since 2020. The OIG was told that due to COVID, the CensiTrac coordinator was not trained in the use of CensiTrac and that the

[33] VHA Directive 1003, *VHA Veteran Patient Experience*, April 14, 2020. "Just culture is an environment that balances the need for an open and honest reporting environment with the end goal of organizational and behavioral improvement." VHA National Center for Patient Safety, "VHA's journey officially begins," accessed February 4, 2021, https://www.patientsafety.va.gov/features/VHA_s_HRO_journey_officially_begins.asp. "HROs put procedures and protocols in place that maximize safety and minimize harm."

[34] VHA Deputy Under Secretary for Health for Operations and Management, "Instrument Tracking Systems for Sterile Processing Services," memorandum to Veterans Integrated Service Network Directors, January 1, 2019. "The CensiTrac® Instrument Tracking System (ITS) [ ] is the defacto standard ITS that all facilities shall utilize."

[35] VHA Directive 1116(2); VHA Directive 1116.

CensiTrac administrative function was not utilized and the program was outdated.[36] Of note, this finding was cited in a 2020 OIG review, a 2021 VISN Consultative Visit, and a 2021 VISN 7 Tiger Team review.[37] These failures jeopardize patient safety, the continuity of RME processes, and are contrary to VHA requirements.

## Failure to Control Traffic Flow in Sterile Areas

VHA states that, "People flow (traffic flow) must be controlled to minimize contamination of the environment due to microorganisms present on human bodies and clothing. Maintaining environmental integrity is accomplished through traffic control in SPS."[38] Interviews with staff revealed that staff were eating, drinking, and storing food in sterile storage areas. In 2020, the OIG identified concerns specific to a beverage found in the dental SPS preparation area and made a broad recommendation for the ADPCS to evaluate and determine reasons for noncompliance and "verif[y] that eating, drinking, and food item storage is prohibited where the processes of decontamination, sterilization, or clean and sterile storage are performed." To close the recommendation, the chief of quality, safety, and value attested on September 13, 2021, to inspecting the "decontamination, sterilization and clean and sterile storage areas in Sterile Processing for food and drink from September 2020 [through] June 2021" and found them to be "in compliance." The spreadsheet that accompanied the chief's statement reflected that almost weekly inspections were conducted.

Of note, on April 29, 2021, after renovation of the SPS area, the infection control coordinator sent an email to the facility chief of safety, and copied the chief of quality, safety, and value, RME coordinator, and the acting SPS chief, which stated

> there is a big open room with sterile instruments and people are just walking through right next to it with their lunch on the way to the conference/break room. This has to be addressed as soon as possible – I don't know how that happened when we made the plans, but the clean instruments can't be considered to remain clean if we don't store them in a protected area where general traffic does not just walk through. The copier is also located in that area. . .so that brings a lot of traffic (germs) into the space where our clean instruments are stored. This **will** be a finding when we are audited/surveyed. Our RME is not being stored in a manner to prevent cross contamination [emphasis in original text].

[36] "COVID-19 (coronavirus disease 2019) is a disease caused by a virus named SARS-CoV-2…COVID-19 most often causes respiratory symptoms that can feel much like a cold, the flu, or pneumonia. COVID-19 may attack more than your lungs and respiratory system. Other parts of your body may also be affected by the disease. Most people with COVID-19 have mild symptoms, but some people become severely ill." CDC, *About COVID-19,* accessed February 28, 2024, About COVID-19 | CDC.

[37] VA OIG, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*.

[38] VHA Directive 1116(2); VHA Directive 1116.

The chief of quality, safety, and value attested to inspecting the SPS sterile storage area at least eight times *after* the concerns were brought forward by the infection control coordinator. This attestation was part of a response from VHA to the OIG as evidence that the recommendation from the previous OIG report could be closed because the facility was in compliance with VHA policy. However, although the chief of quality, safety, and value may not have specifically observed food or drinks in the SPS areas during the eight inspections, the OIG would have expected continued follow-up. The unsuitable physical layout that allowed uncontrolled traffic flow and included a conference room where staff did bring in food and beverages, should have prompted the chief of quality, safety, and value's concern.

In March 2022, while on-site, the OIG observed the area referenced by the infection control coordinator—a staff conference and training room, equipped with a refrigerator and microwave oven, located at the opposite end of a large SPS sterile storage area. Staff continued to use the area for lunch or breaks and, because of its location, were still bringing their food and beverages through the sterile storage space. This presents a risk for contamination and breach of environmental integrity in SPS.[39]

According to an OIG interview with the facility chief engineer, the options to bring the facility into compliance with VHA requirements were expensive (remodel) or inconvenient (would preclude staff from using the training room as a lunchroom).

## SPS SOPs Were Not Updated and Accessible to Staff

During the OIG's unannounced March 2022 inspection of clinics where the SPS processes of decontamination, sterilization, or clean and sterile storage are performed, OIG team members observed that in some areas, the current facility SPS SOPs were not based on manufacturer's guidelines, updated, or consistently available. In addition, the OIG found end-user staff were not always able to identify the location of current SPS SOPs within their work area.[40]

VHA requires the development and dissemination of reprocessing SOPs and competency assessments for all critical and semi-critical RME. The SOPs are required to be in alignment with the manufacturer's IFU. In addition, SOPs must be reviewed at least once every three years, updated when there is a change in process or a change in manufacturer's IFU, and consistently accessible to all staff at all times.[41]

The acting chief of SPS told the OIG during an interview that prior to January 2022, the development and updating of the SPS SOPs was the responsibility of the RME coordinator, with

[39] This finding was also cited in a 2020 OIG review, a 2021 VISN Consultative Visit, and a 2021 VISN 7 Tiger Team review.

[40] *Merriam-Webster.com Dictionary,* "end-user," September 12, 2023, https://www.merriam-webster.com/dictionary/end%20user. An end-user is the ultimate consumer of a finished product.

[41] VHA Directive 1116(2); VHA Directive 1116.

the acting chief of SPS and ADPCS's review and signature. The acting chief of SPS went on to say that the process had changed and that, while the RME coordinator is still responsible for the development and updating of the SPS SOPs, they are now vetted and voted on at the RME monthly meetings, and the infection control nurse is an additional signer.

The OIG was told in an interview with the facility RME coordinator, that prior to transferring to SPS in March of 2020, the coordinator worked as a staff nurse and had no prior SPS experience. The RME coordinator went on to say that formal training was not provided due to COVID, but reported completing online certification courses. The RME coordinator also reported as being "pretty much on my own as far as learning what was expected of me."

The failure to ensure that current and accessible SPS SOPs were available facility-wide was identified in a 2019 NPOSP review, a 2020 OIG review, and a 2021 VISN-led SPS consultative visit.[42] At the time of the OIG's site visit in March 2022, the facility had not resolved the SPS SOP issues. The OIG concluded that unstable or vacant leadership positions in SPS and the failure of facility leaders to provide resources, support, or training contributed to the RME coordinator's inability to successfully resolve this issue.

## SPS Staff Did Not Receive Appropriate Training

Based on interviews and document reviews, the OIG determined that significant training and competency failures existed. For example, a 2018 Deputy Under Secretary for Health for Operations and Management memorandum (2018 Memo) required all facilities to identify RME champions to serve as the point of contact for RME end-users and clinical staff, as well as serve as ad hoc members on RME committees.[43] The OIG found that, despite the requirements outlined in the 2018 Memo, facility RME champions had not been identified nor received training until February 2022. Further, the OIG determined during interviews with SPS staff and the MST trainer that SPS training was ineffective, and staff responsible for RME reprocessing were not fully attentive or engaged in the training.

VHA requires SPS employees and others with cleaning responsibilities to participate in continuing education and ongoing competency assessments to validate employee proficiency for specific cleaning and RME reprocessing tasks, as appropriate.[44] Competency assessments focus

[42] VA OIG, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*.

[43] VHA Deputy Under Secretary for Health for Operations and Management, "Clarification of Reusable Medical Equipment Committee Oversight and Membership Requirements" memorandum to Network Directors, Chief Medical Officers, Quality Management Officers, and VISN Nurse Sterile Processing Boards, January 23, 2018. "RME Champions identified within each service line will serve as a "go-to" point of contact for facility staff when addressing RME matters specific to the service line. The purpose of the Champion is to ensure the appropriate handling of RME in clinical areas and share technical knowledge from the clinician's perspective as an active/ad hoc member of the RME Committee."

[44] VHA Directive 1116(2); VHA Directive 1116.

on new RME items or procedures, new technologies, and changes to existing manufacturers' IFUs, among other areas. Typically, IFUs are used in the creation of device-specific SOPs, and those SOPs are used for competency assessment. Changes and updates to manufacturer reprocessing standards are issued via email from NPOSP to various VISN and facility groups that include SPS chiefs, assistant chiefs, and other designees. According to an electronic correspondence from the VISN SPS lead, the information is to be disseminated to appropriate VISN- and facility-level trainers and end-users.

The SPS chief and ADPCS have broad responsibility for ensuring compliance with training and competency requirements to ensure safe and effective SPS operations. In addition

- the SPS quality assurance nurse is responsible for performing clinical nurse observation rounds in the SPS areas weekly to validate processes and identify educational needs of staff;
- the RME coordinator is responsible for identifying, planning, implementing, and evaluating evidence-based changes to the RME practice content, as well as collaborating with others to improve care by sharing expertise and implementing current research findings; and
- the MST trainer is responsible for developing written plans for the SPS training program, facilitating training of SPS staff through educational programs and job-specific instruction, and assessing staff training and needs.

The OIG found that individuals in these roles were not consistently effective in ensuring safe, competent RME-related practices. The OIG based this determination on discussions, document reviews, and EOC observations that revealed either an underlying lack of knowledge about what constitutes a deficient condition, or a complacency about the need to learn more and follow-up. For example, an MST reported being told by the lead SPS technician it was acceptable practice to re-store an unused endoscope. In addition, the OIG observed a dirty SPS cart in a clean storage area and a filing cabinet in a clean and sterile storage area.

Further, during interviews, one SPS employee told the OIG that training sessions were not consistent or effective, and the MST trainer told the OIG of feeling as if "people. . .do not care about the job" the MST trainer does, that training is "pointless," and that SPS employees are not interactive during training sessions. The MST trainer stated there was no preceptor program at the facility but was trying to precept new employees in order to keep the process consistent and simple across the board; however, the training did not appear to be consistent. An Augusta operations team lead told the OIG of thinking that facility SPS employees' had a lack of

knowledge and were reprocessing equipment incorrectly, perhaps because they had been told they could do it that way or they had been doing it that way for so long.[45]

The MST trainer also told the OIG that, prior to starting the position, competencies were not consistently completed from 2017 until March 2021. The OIG reviewed SPS employee training and competency folders for fiscal year 2022 and confirmed inadequate documentation of staff competencies.

The OIG learned through interviews that as of February 2022, in consultation with VISN SPS leaders and trainers, all SPS SOPs and competencies were in the reformatting and updating process. The OIG learned from the acting chief of SPS that as of February 2022, reformatting was complete for 30 SOPs, and competency assessment was underway but incomplete. The OIG noted, however, that the list of competencies did not include Spaulding Classification or competency review frequency.[46] When questioned about this, the MST trainer told the OIG of having intuitive knowledge of each competency review frequency based on the risk assessment but acknowledged that this could be a vulnerability and subsequently planned to add this information to the competency list.

The OIG determined that SPS lacked a fabric of teamwork and collegial support that are fundamental to ensuring "a continuous flow of processed critical and semi-critical instruments to all points of use" and that reusable soiled items returned to SPS are "handled in a manner conducive to patient and staff safety. . ." The OIG concluded that the compounding effects of leadership instability and ineffectiveness, a culture of complacency and conflict within SPS, and deficiencies in SPS training and competency assessments contributed to an inefficient and difficult work environment.

## Abnormal Critical Water System Test Results Were Not Addressed Timely

The OIG found that a series of practice failures, along with a culture of complacency and unaccountability, resulted in a deficient water management program at the facility. This was further exacerbated by the lack of facility and VISN SPS policies. The sequence of events related to the critical water testing results is outlined in figure 1 below.[47]

[45] The Augusta operations team lead told OIG of having the sense that facility SPS staff would be able to maintain the correct processes now that "we start the staff doing it more and more and more and more, they catch on to it."

[46] VHA Directive 1116(2); VHA Directive 1116. "Critical items (Spaulding Classification System) are instruments or objects introduced directly into the bloodstream or other normally sterile body areas." "Semi-critical items (Spaulding Classification System) are those that come in contact with non-intact skin or mucous membrane."

[47] VHA Assistant Under Secretary for Health for Operations, "Required critical water systems testing and reporting for Sterile Processing Services (SPS)," memorandum to Veterans Integrated Service Network (VISN), Directors, VISN Chief Medical Officers, VISN Quality Management Officers, and VISN Sterile Processing Services Leads, August 28, 2020. The bacteria in the critical water testing is to be less than 10 colony-forming units and tested monthly; however, it was consistently found to be over the limit.

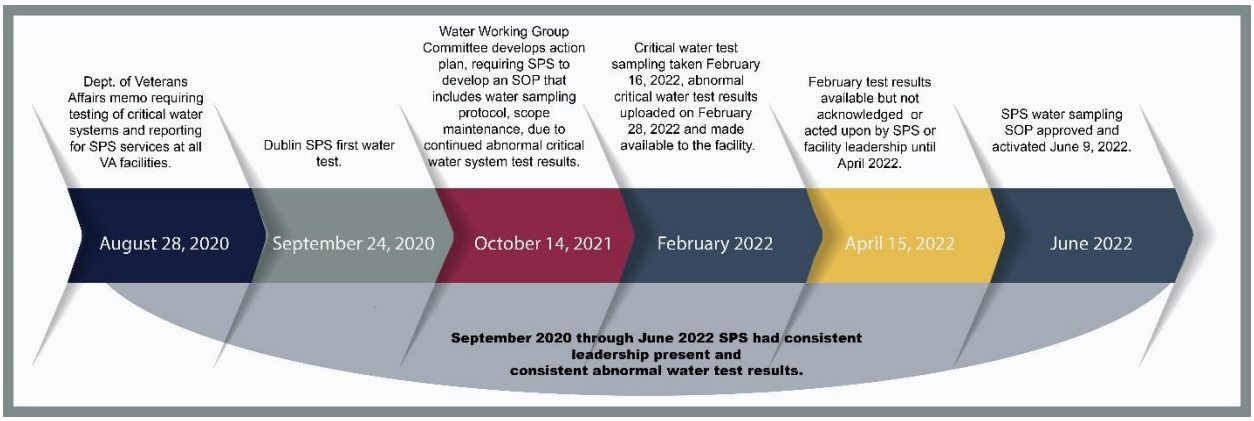


***Figure 1.*** *Critical Water Testing Timeline*
*Source: Information obtained from interviews, emails, meeting minutes, water test results, and required critical water systems testing and reporting for the SPS memorandum.*

VHA facilities are required to perform critical water system testing as defined in the Association for the Advancement of Medical Instrumentation Technical Information Report 34. In addition, facilities are required to "have a program in place for testing and performing routine preventative maintenance on the critical water system" and to institute corrective measures when needed. The VISN SPS Management Board is responsible for ensuring the facilities are meeting the requirements.[48] VISN 7 utilizes a third-party contractor to conduct routine and abnormal critical water system testing at all eight of its facilities. To ensure that abnormal critical water values are addressed appropriately, VHA requires that all routine and abnormal critical water system results are reported to the VISN SPS Management Board. All corrective actions developed in response to abnormal critical water system results are required to be reported to the NPOSP by the VISN SPS Management Board.

Through interviews, the OIG learned it is the facility liaison's responsibility, as the only one with access to the system, to check the contractor's web-based system and upload the results to the facility site that designated facility leaders can access. The OIG found that the facility liaison responsible for communicating information between the contractor of the water management program and the facility, failed to effectively communicate the contractor's notification of abnormal critical water testing results to the facility Water Working Group and facility leaders. According to electronic correspondence provided by the acting Associate Director, there was an acknowledgment of a delay in facility leaders notifying VISN leaders after implementing a curtailment of services as a result of the abnormal results.

[48] Association for the Advancement of Medical Instrumentation Technical Information Report (AAMI) (TIR) 34:2014 (R)2017, reaffirmed December 12, 2017, *Water for the reprocessing of medical devices*. Utility water is "water as it comes from the tap that may require further treatment to achieve the specifications. This water is mainly used for flushing, washing, rinsing."

According to the water management contract, the contractor of the water management program is responsible for entering critical water test results into a web-based system within 10 days of the test. In addition, the contractor is expected to email the critical water test results to the facility liaison. The liaison, who is co-chair of the Water Working Group, is also responsible for providing members of the Water Working Group with the critical water test results. In an interview with an employee of the contractor, the OIG learned that facility leaders are then expected to review the results and call an emergency Water Working Group meeting if remediation is needed.

The critical abnormal water test results from February 16, 2022, were available to the facility liaison on February 28, 2022; however, the results were not acted upon with any sense of urgency. The OIG was told the liaison did not notify facility leaders that test results had been uploaded to the facility shared site, nor did facility leaders check the shared site for results.

The acting Associate Director told the OIG of being informed on April 15, 2022, about the February 2022 abnormal critical water test results and consulting with the facility liaison.[49] An emergency Water Working Group meeting was held that same day and a decision was made to curtail services and retest the critical water system. While reviewing documentation received from the facility and the water management program contractor, the OIG identified that the facility had consistently abnormal critical water test results dating back to September 2020. Based on a review of the Water Working Group meeting minutes, the OIG determined that facility and SPS leaders were aware of the concerns related to water testing but did not effectively implement actions to address the concerns. At no point during that two-year period were remediation attempts initiated in order to correct the abnormal critical water test results.

In light of facility and SPS leaders' awareness of the long-standing abnormal results, the OIG requested documentation from the facility and VISN to ensure compliance with the VISN notification requirement. Despite repeated requests by the OIG, facility staff did not provide documentation. In reviewing the documentation provided by the VISN, the OIG was unable to determine whether all routine and abnormal critical water test results were submitted by the facility and reviewed by the VISN SPS Management Board over the last two years. In addition, the Director, VA Office of Healthcare Engineering told the OIG that facility leaders failed to consult the VA Office of Healthcare Engineering upon learning of consistently out of range results. The Director explained that, generally, at facilities with repeated abnormal critical water test results, the office gets involved when the facility cannot resolve the issue themselves.[50]

[49] The acting Associate Director was the acting Facility Director on April 12, 2022.

[50] VHA Directive 1061, *Prevention of Health Care-Associated Legionella Disease and Scald Injury from Water Systems*, February 16, 2021.

In October 2021, the acting SPS chief was charged by the Water Working Group with creating an SPS SOP that defines the water management process.[51] The acting Associate Director told the OIG that as of April 2022, the SOP was still in draft form. In addition, the VISN SPS lead told the OIG that a VISN water management policy was also in the draft process. Prior to the OIG's review, the VISN did not have a policy. Although not required, a facility and VISN water management policy may have helped mitigate the scope of abnormal critical water test results, as well as prevent the curtailment of services resulting from the abnormal results.

## Interim and Acting Leadership Negatively Impacted SPS Culture

In SPS, leaders are responsible for overseeing the sterilization and high-level disinfection of critical and semi-critical RME and providing oversight of SPS staff. Over the past several years, both the SPS chief and SPS assistant chief positions were temporarily filled with interim or acting staff. The SPS chief position has been filled by two acting chiefs since 2018. The current acting SPS chief, who had served in that role since October 2020 and declined the permanent position, told the OIG of not having prior experience in SPS. Further, the assistant chief position has been filled twice since June 2019. A former permanent assistant chief was hired in April 2021 but resigned in August 2021. At the time of the OIG's inspection, interviews for the SPS chief position were being conducted. A new permanent assistant chief was scheduled to start June 19, 2022, and the new permanent chief entered on duty on July 5, 2022, according to electronic correspondence provided to the OIG by the chief of quality, safety, and value.

According to The Governance Institute, leaders "establish the organization's culture through their words, expectations for action, and behavior," and "leaders of an organization are the most powerful force in changing the organization's culture and in eliminating intimidating behavior."[52] A 2019 NPOSP report recommended that the facility "fill key positions as a priority," including the chief, assistant chief, and lead technician positions in SPS. The OIG found that the series of acting or short-term staff in the SPS chief and assistant chief positions may have contributed to the facility's failure to focus on the monitoring and management of SPS challenges.

In addition, the OIG found the culture within SPS did not consistently support a commitment to teamwork and the pursuit of achieving SPS's mission. Culture is "a set of behaviors, beliefs,

[51] The Water Working Group is a multidisciplinary group responsible for continuous assessment and reporting of water quality as it relates to biocide levels, temperature, cleaning, and taking action to notify facility leaders of water results. The facility refers to both the Water Working Group and Water Safety Committee; however, they are the same group.

[52] A Governance Institute white paper, "Leadership in Healthcare Organizations, second edition: A Guide to Joint Commission Leadership Standards," 2017.

policies, and actions that are regularly implemented within a particular setting." The collective elements of culture affect the efficiency and timeliness of day-to-day work.[53]

The OIG reviewed AIB transcripts, external reviews, and discussed with SPS staff how they perceived the overall culture in SPS. Multiple staff members reported a culture of intra-departmental conflict, a difficult work environment, and racial divide. For example, two staff members were previously detailed outside of SPS for engaging in a verbal altercation; both staff members have since returned to SPS. Allegedly, MSTs were encouraged by fellow MSTs not to help each other, and a supervisor was not seen as helpful or engaging and as spending most of the workday in their office. In addition, multiple staff members made conflicting statements about what happened and who was responsible for the alleged actions on January 4, 2022.

The OIG confirmed that a culture of complacency and unaccountability existed both with the front-line staff and at the SPS leadership level. For example, during EOC rounds in the SPS clean and sterile storage room, the OIG found that staff were unable to locate the wall mounted humidity monitor. An OIG team member found the humidity monitor on the floor against the wall, and an SPS staff member made a comment questioning if that was the monitor that fell off the wall last week. No one had considered returning the monitor to the wall until the OIG questioned its location.

The OIG also found that SPS leaders and staff had not fully incorporated the concept of Just Culture. For example, the OIG noted that employees within SPS did not Stop the Line on January 4, 2022, as would have been expected of an organization striving for high reliability and a culture of safety; rather, they waited several days and made the allegation during the AIB interview process. The SPS team held a virtual meeting in January 2022, where the acting SPS chief said that it was apparent that staff do not feel psychologically safe to speak up. As a result, several activities were initiated with SPS staff including daily huddles, and Stop the Line/See Something Say Something training. On April 14, 2022, the acting SPS chief provided electronic correspondence confirming that 100 percent of facility SPS staff had completed Stop the Line training.

## Issue 2. EOC Concerns

The OIG conducted EOC reviews of all areas where RME was utilized, and identified several deficiencies.[54] The OIG found concerns with a culture of complacency among facility and SPS leaders who failed to address previously identified issues with a sense of urgency or purpose.

[53] Standards of Care, *Healthcare Culture*, accessed February17. 2021, https://www.standardsofcare.org/healthcare/culture/.

[54] The OIG did not conduct an in-depth review of the primary SPS reprocessing area because, at the time of the OIG's site visit, SPS reprocessing operations were being performed by SPS staff from other VHA facilities with assistance from facility SPS staff.

The proper storage of clean and sterile supplies is essential in preventing contamination and patient infections, as well as product deterioration. To maintain supplies properly, sterile storage rooms must have stable temperature and humidity, restricted access, and solid bottom shelves at least eight inches from the floor.[55]

VHA Directive 1116(2) requires that

- "air flow is carefully controlled in SPS to minimize the movement of microorganisms from dirty areas to clean areas;"
- "all nursing units and clinic areas are to have a designated soiled utility room. Designated soiled utility rooms can be shared space between units, if necessary. Enclosed containers must be provided in these rooms. All clinical procedure trays and other critical and semi-critical RME must be placed in these containers;"
- "contaminated items should be contained before transport through the medical facility to minimize airborne or contact spread of microorganisms, and to reduce the risk of cross-contamination and infection. Reusable collection containers must be biohazard, medical grade, puncture resistant, rigid, made of material that can be properly cleaned and decontaminated and must contain a lid;"
- case carts used in the storage and transport of soiled surgical instruments must be enclosed; and
- "the SPS areas must be kept free of insects, rodents, and other vermin."

During the March 2022 unannounced site visit, the OIG completed physical inspections and interviewed staff within the following areas: SPS; dental, radiology, podiatry, and optometry; operating room; and endoscopy; as well as the corresponding sterile storage areas.

**Table 2. EOC Concerns**

| EOC Location | Concern | Why It Matters |
|---|---|---|
| Dental clinic | • Inconsistent compliance with negative/positive pressure, ventilation, temperature, and humidity requirements for clean/sterile and soiled utility room | • Risk for contamination<br>• VHA requirement |
| Operating room | • No designated soiled utility room to rinse or clean soiled instruments and did not have a dedicated sink for handwashing after handling soiled instruments | • Risk for cross contamination and infection control<br>• VHA requirement |
| Radiology department | • No SPS cart to place soiled vaginal probes and soiled | • Risk for cross contamination |

[55] VHA Directive 1116(2); VHA Directive 1116.

| EOC Location | Concern | Why It Matters |
|---|---|---|
| | probes placed on clean linen cart in patient care area | • VHA requirement |
| Optometry, Podiatry, Urology, and Primary Care departments | • Clean and sterile storage room contained both clean and dirty equipment | • Risk for cross contamination<br>• VHA requirement |
| Endoscopy clinic Decontamination area | • SPS staff did not follow personal protective equipment (PPE) requirements in the decontamination area | • Risk for cross contamination<br>• VHA requirement |

*Source: OIG EOC round observations at CVVAMC March 2022. VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016; VHA Directive 1116, Management of Critical and Semi-Critical Reusable Medical Devices, July 17, 2023.*
*Note: Throughout this table, any reference to "VHA requirement" refers to VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016; VHA Directive 1116, Management of Critical and Semi-Critical Reusable Medical Devices, July 17, 2023.*

## Dental

Electronic correspondence provided by the chief of quality, safety, and value states that the dental clinic was closed for construction on January 25, 2022, and reopened on April 26, 2022. When observing the dental clinic, the OIG identified several EOC-related concerns.

In August 2021, the dental clinic had received three new cabinets for storage of dental RME and the cabinets were located in the clean and sterile storage room; however, at the time of the OIG's visit, only one cabinet was working. In a discussion with the RME champion, a dental hygienist, the hygienist was not able to accurately identify which sterile and soiled utility rooms required positive versus negative air pressure.[56] The dental clinic also had issues with air pressure, and the VISN previously identified ventilation, temperature, and humidity within the SPS storage rooms as not consistently being compliant with requirements.

The soiled utility room, which requires negative pressure, was under positive pressure during the OIG's site visit.[57]

The OIG interviewed the facility chief of engineering service about the issues, including the challenges of keeping the temperature and humidity in the clean and sterile storage room and

[56] Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008, updated May 2019, accessed June 6, 2021, https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Negative pressure is recommended for storage of dirty instruments, and positive pressure is recommended for sterile instruments.

[57] The soiled utility room was full of instruments that needed to be disposed of permanently, and instruments that would need to be reprocessed by SPS prior to being used in the dental clinic.

soiled utility room within range.[58] During an EOC rounding discussion, the OIG learned that the acting chief of the dental department had drafted an SOP for the Jade Air Purifier, effective March 8, 2022, and the SOP is housed on the facility SharePoint site.[59]

## Radiology

The OIG found that the radiology department did not have a designated soiled utility room even though this deficiency had been identified during a VISN SPS/RME site visit in August 2021. In addition, the OIG found that the department had no SPS carts to store dirty instruments although staff told the OIG that the SPS carts had been requested.

An example provided by staff explaining how this has presented a challenge was in the storage of transvaginal probes. Each week, radiology department staff perform five to six vaginal ultrasounds using transvaginal probes. Radiology staff reported to the OIG that dirty transvaginal probes were stored in SPS-provided locking bins with lids; these bins were stacked on top of a clean linen cart because radiology did not have an SPS cart to store soiled probes.

## Operating Room

In the operating room, the OIG identified a dirty SPS cart near a scrub sink between two suite doors. Operating room staff explained to the OIG that there is no soiled utility room back where the surgical suites are located to store the dirty SPS cart; the operating room's soiled utility room is located in the entrance to the surgical suite. In addition, operating room technicians had no designated place to rinse or pre-clean instruments. As a result, technicians sprayed foam on dirty instruments inside the boxes in the dirty SPS cart located between two suite doors, which is a designated clean area within the operating room. Operating room technicians also did not have a dedicated sink to wash their hands after handling soiled instruments. Once again, this presents a potential for cross contamination, which is an infection control issue.

After the site visit, the OIG was notified by electronic correspondence from the operating room nurse manager that the dirty SPS cart is located in the soiled utility room. After each surgical case, the used RME is taken out of the operating room surgical suite and placed in that cart. Additionally, the technicians have a dedicated sink to wash their hands.

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[58] VHA Directive 1116(2); VHA Directive 1116. "Storage areas for critical and semi-critical RME require temperature 66-75 [Fahrenheit], humidity 30–55 percent, with positive filtration and four air exchange parameters in order to protect RME integrity. A monitoring system capable of documenting continuous humidity and temperatures is required in all SPS areas."

[59] The Jade Air Purifier When the DC fan motor is running, the indoor air will be drawn through the bottom of the unit. The air will then pass through the HEPA-Rx Filter, the Activated Carbon Filter and the Germicidal UV-C+ Photocatalytic Nano-TiO2 chamber. The purified air is then released through the outlet on the top of the unit. The Revitalizing Negative Ion Generators near the air outlet releases revitalizing negative ions into the air to refresh the air.

During the site visit, the OIG also witnessed an insect flying near the operating room ceiling outside the operating room suite doors. An operating room technician told the OIG that bees and yellow jackets appear periodically all year round and work orders have been submitted, but nothing has been done. The chief of engineering and the chief of staff claimed they did not know about the insect problem.

## Optometry, Podiatry, Urology, and Primary Care Departments

At the facility, Optometry, Podiatry, Urology, and Primary Care share a clean and sterile storage room and a soiled utility room. The OIG found that the sterile storage room contains supply racks that lack solid bottom shelves as required to reduce cross contamination from the floor. In addition, the supply racks were less than two inches from the wall where condensation could impact the integrity of equipment and supplies. The OIG found the soiled utility room contained both clean and dirty equipment; this is concerning because cross contamination is a potential infection control issue.

In addition, one podiatry provider explained to the OIG the practice of collecting the RME and supplies needed for future procedures to be performed in the clinic over several days and keeping them in the procedure rooms. The RME and supplies that are not used or opened are returned to the clean and sterile storage room. However, this practice is contrary to VHA policy.[60]

## Endoscopy

According to VHA,

> each area within SPS has a dress code that must be strictly adhered to in order to prevent cross contamination and to protect the employee. Sterile processing service (SPS) staff who participate in completing tasks associated with the cleaning and decontamination of reusable medical equipment (RME) are subject to hazards. It is the responsibility of the chief, SPS to ensure SPS employees are provided with PPE and training on the appropriate use of PPE. . . . PPE worn while working in the decontamination area is not to be worn in any other area of SPS or the medical facility. All PPE must be removed prior to leaving the decontamination area.[61]

[60] VHA Directive 1116(2); VHA Directive 1116.

[61] VHA Acting Deputy Under Secretary for Health for Operations and Management, Work Attire and Personal Protective Equipment (PPE) Requirements for Sterile Processing Service, memorandum to VISN Directors and VISN Sterile Processing Boards, August 5, 2015. "Entry into any decontamination area without the designated PPE is prohibited at all times, regardless of the level of activity being performed at the time of entry." "According to The Occupational Safety and Health Administration (OSHA), PPE is defined as specialized clothing or equipment worn by an employee for protection against a hazard."

Endoscopy suite staff told the OIG that endoscopy staff place soiled endoscopy scopes in the dirty SPS cart, which is located outside of the reprocessing room in the adjacent hallway. From that point, SPS staff are responsible for retrieving dirty scopes from the cart for reprocessing.

While on-site, the OIG observed the staff's process in practice and witnessed a member of the SPS staff working in the decontamination (cleaning) room open the decontamination room door, step outside into the hallway, open the soiled container, take out the soiled endoscopes, and return to the cleaning area. The SPS MST did not change PPE upon stepping out of the decontamination room into the hallway, as required. The purpose of the dress code is to prevent cross contamination and to protect the employee. Of note, the endoscopy suite does not have an area where all protective clothing can be removed and properly stored or disposed of. The SPS MST did not change PPE when exiting the decontamination room and entering the hallway, thus increasing the possibility of cross contamination and exposing the MST to a potential risk of infection.

The OIG determined that the facility was aware of similar EOC issues that had been identified in prior inspections conducted by the NPOSP, VISN, and OIG. However, the facility was unable to provide action plans for several of the previously identified EOC issues, including remediation of the location and use of the training room in the SPS clean and sterile storage room and the lack of a soiled utility room for Radiology, either specific to the department or shared with other clinics. As of the OIG's visit, these issues remained unresolved. Given the long-standing deficient EOC conditions, the OIG concluded that the SPS culture and processes did not support and promote collective problem-solving. As such, there is no assurance that the integrity of sterile supplies was maintained.

# Conclusion

SPS serves a critical function in ensuring that essential high-level disinfection or sterilization of RME occurs to prevent the transmission of infectious pathogens to patients. The failure to properly clean, test, disinfect, or sterilize equipment carries significant risk for person-to-person transmission of infectious diseases.

Although the OIG determined that facility and VISN leaders took appropriate and timely actions *after* learning of the endoscope issue on January 4, 2022, the OIG found that VISN, facility, and SPS leaders had enabled a culture of complacency and unaccountability due to their failure to address deficient conditions that ultimately resulted in increased patient safety issues within SPS. Many of the deficient conditions discussed in this report were cited in previous external reviews. Additionally, several of the conditions were conspicuous and should have been identified by responsible employees with an understanding of RME-related guidance. The failure of facility leaders to address deficient conditions when they were initially identified, coupled with a weak SPS safety culture and noncompliant operational processes, repeatedly placed patients at risk for poor clinical outcomes and "set the stage" for the large-scale disclosure to over 6,600 veterans in

this case. The OIG also found that these underlying conditions resulted in several RME-related EOC deficiencies, as well as a deficient water management program at the facility.

Ultimately, the OIG is concerned that consistent oversight and evaluation of direct program activities as well as those programs that support SPS functions, commensurate with the critical nature of the SPS program, are not being provided by the VISN or facility leaders.

# Recommendations 1–9

1. The Carl Vinson VA Medical Center Director ensures that the Sterile Processing Services chief conducts comprehensive staff competency assessments for the reprocessing of reusable medical equipment, and monitors for compliance.
2. The Carl Vinson VA Medical Center Director ensures that the CensiTrac Instrument Tracking System is fully implemented, and that training is provided to the CensiTrac coordinator and Sterile Processing Services staff, and monitors for compliance.
3. The Carl Vinson VA Medical Center Director evaluates and ensures that Sterile Processing Services maintains a safe and clean environment in all areas where decontamination, sterilization, or clean and sterile storage of reusable medical equipment are performed, and monitors for compliance.
4. The Carl Vinson VA Medical Center Director develops an action plan for remediation of the location and use of the training room adjacent to Sterile Processing Services' clean and sterile storage area, and monitors for compliance.
5. The Carl Vinson VA Medical Center Director ensures that clinic areas, including radiology, have or share a designated soiled utility room as required by Veterans Health Administration policy, and monitors for compliance.
6. The Carl Vinson VA Medical Center Director ensures that Sterile Processing Service standard operating procedures for reusable medical equipment are developed, updated consistent with manufacturer's instructions for use, disseminated, and available at the point of use, and monitors for compliance.
7. The Veterans Integrated Service Network Director reviews the facility's Sterile Processing Service water management program and takes action as necessary to ensure compliance with Veterans Health Administration guidance, and monitors for compliance.
8. The Carl Vinson VA Medical Center Director ensures that the facility Water Working Group submits critical water system test results to the Veterans Integrated Service Network Sterile Processing Services Management Board, as required, and monitors for compliance.
9. The Veterans Integrated Service Network Director ensures all critical water system test results are reviewed by the Veterans Integrated Service Network Sterile Processing Services

Management Board, corrective action is taken when appropriate, and all corrective actions are reported to the National Program Office for Sterile Processing, and monitors for compliance.

# Appendix A: VISN Director Memorandum

## Department of Veterans Affairs Memorandum

Date: February 2, 2024

From: Director, VA Southeast Network (10N07)

Subj: Healthcare Inspection—Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia

To: Director, Office of Healthcare Inspections (54HL00)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have completed a full review of the Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia draft report and concur with the findings.

2. I concur with the recommendations and action plan submitted by the Carl Vinson VA

Medical Center in Dublin, Georgia for recommendations 1-6, and 8. In addition, I concur with VISN 7's action plan for recommendations 7 and 9.

3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.

4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

(*Original signed by:*)

David M. Walker, MD, MBA
Network Director

# VISN Director Response

## Recommendation 7

The Veterans Integrated Service Network Director reviews the facility's Sterile Processing Service water management program and takes action as necessary to ensure compliance with Veterans Health Administration guidance, and monitors for compliance.

Concur_X__

Nonconcur___

Target date for completion: April 30, 2024

### Director Comments

The Veterans Integrated Service Network Director will ensure the facility's Sterile Processing Service Water Management Program is compliant through a review of the VHA guidance on the next SPS site visit scheduled for March 2024 and the establishment of facility level standard operation procedure (SOP). The tracking of the completed SOP and SPS site visit will be tracked and monitored by the Network Director in Quality and Patient Safety Committee (QPSC). Any corrective actions from the SPS review will be tracked for actions and compliance through QPSC.

## Recommendation 9

The Veterans Integrated Service Network Director ensures all critical water system test results are reviewed by the Veterans Integrated Service Network Sterile Processing Services Management Board, corrective action is taken when appropriate, and all corrective actions are reported to the National Program Office for Sterile Processing, and monitors for compliance.

Concur_X__

Nonconcur___

Target date for completion: July 2024

### Director Comments

The Veterans Integrated Service Network Director will ensure critical water system test results are reviewed by the Veterans Integrated Service Network Sterile Processing Services Management Board. The VISN Chief Sterile Processing Officer (CSPO) will receive and review critical water testing results in the VISN SPS Management Board. The receipt of the full report and reporting of the critical water results will be initiated in February's Veterans Integrated Service Network Sterile Processing Services Management Board meeting and replace prior water

reporting. Any corrective actions will be documented in the minutes and tracked for compliance. The CSPO will develop a dashboard to report monthly critical water testing results to the Network Director in QPSC.

# Appendix B: Facility Director Memorandum

## Department of Veterans Affairs Memorandum

Date: January 16, 2024

From: Director, Carl Vinson VA Medical Center (557/00)

Subj: Healthcare Inspection—Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia

To: Director, VA Southeast Network (10N07)

1. Thank you for the opportunity to review and comment on the Office of Inspector General, Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia. I concur with the recommendations in the report.

2. Carl Vinson VA Medical Center remains committed to ensuring our Veterans receive health care of the highest quality.

(*Original signed by*:)

David Scott Reesman, LTC, Army (R)
Executive Director (Interim)
Dublin VA Healthcare System

# Facility Director Response

## Recommendation 1

The Carl Vinson VA Medical Center Director ensures that the Sterile Processing Services chief conducts comprehensive staff competency assessments for the reprocessing of reusable medical equipment, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: March 31, 2024

### Director Comments

The Medical Center Director evaluated this recommendation and found no additional reasons for noncompliance. In April of 2022, the Sterile Processing Services, Chief and Sterile Processing Services trainer developed and implemented a Comprehensive Staff Competency Assessment Tracker and it is evaluated annually with the Risk Analysis. The Risk Analysis is reported out annually in the Reusable Medical Devices Oversight Committee. Once the Risk Analysis is completed, the Comprehensive Staff Competency Assessment Tracker is edited to reflect any changes. The Risk Analysis is completed annually and presented in the Reusable Medical Devices Oversight Committee and reviewed during the annual VISN SPS audit. Compliance will be monitored by reviewing Reusable Medical Devices Oversight Committee January 2024 minutes and the VISN SPS audit scheduled for March 2024.

## Recommendation 2

The Carl Vinson VA Medical Center Director ensures that the CensiTrac Instrument Tracking System is fully implemented, and that training is provided to the CensiTrac coordinator and Sterile Processing Services staff, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: Completed.

### Director Comments

The Medical Center Director evaluated this recommendation and found no additional reasons for noncompliance. In September 2023, the Instrument Tracking System Coordinator received training from the client manager for the manufacturer during a site visit. In October of 2023, the Sterile Processing Services, Chief, fully implemented the CensiTrac Instrument Tracking System. Since the initial training in September 2023, the Instrument Tracking System

Coordinator has received additional warranted training from the manufacturer for any identified needs or requests.

### OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

## Recommendation 3

The Carl Vinson VA Medical Center Director evaluates and ensures that Sterile Processing Services maintains a safe and clean environment in all areas where decontamination, sterilization, or clean and sterile storage of reusable medical equipment are performed, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: July 31, 2024

### Director Comments

The Medical Center Director evaluated this recommendation and did not determine any reasons for noncompliance. An Environment of Care tracer is provided by Quality Safety & Value Accreditation Specialist to monitor for compliance. Identified deficiencies from the investigation were corrected. The facility will perform monthly tracers and will be monitored in Quality Executive Council monthly until six consecutive months of one hundred percent compliance.

## Recommendation 4

The Carl Vinson VA Medical Center Director develops an action plan for remediation of the location and use of the training room adjacent to Sterile Processing Services' clean and sterile storage area, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: Completed.

### Director Comments

The Medical Center Director evaluated this recommendation and did not determine any reasons for noncompliance. Sterile Processing Service delivers all reusable medical equipment to the end user where it is stored in a designated clean, sterile, and monitored location. Any reusable

medical equipment in the Sterile Processing Service is stored in a temperature/humidity cabinet that is also stored in a temperature/humidity and traffic-controlled environment.

### OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

## Recommendation 5

The Carl Vinson VA Medical Center Director ensures that clinic areas, including radiology, have or share a designated soiled utility room as required by Veterans Health Administration policy, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: Completed.

### Director Comments

The Medical Center Director evaluated this recommendation and found no additional reasons for noncompliance. In March 2022, the Radiology Service Line and Women's Clinic began calling Sterile Processing Services for on demand pickups. If Sterile Processing Service does not respond within allotted time per the Manufacturer's Instructions for Use, the service staff will place the soiled reusable medical device in the shared designated soiled utility room. All other clinic areas that use reusable medical equipment have a designated soiled utility room.

### OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

## Recommendation 6

The Carl Vinson VA Medical Center Director ensures that Sterile Processing Service standard operating procedures for reusable medical equipment are developed, updated consistent with manufacturer's instructions for use, disseminated, and available at the point of use, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: July 31, 2024

### Director Comments

The Medical Center Director evaluated this recommendation and found no additional reasons for noncompliance. In March 2022, the Sterile Processing Service Chief designated the Sterile Processing Services Trainer to review all point of use standard operating procedures for changes/updates. The Sterile Processing Service Trainer revised all standard operating procedures and competencies to align with the Manufacturer's Instructions for Use. Once the standard operating procedures and competencies were reviewed, they were signed by the Sterile Processing Service Chief and Associate Director for Patient Care Services. The Sterile Processing Service Trainer disseminated the standard operating procedures and competencies to the Reusable Medical Devices Champions for each service area using Reusable Medical Devices. The Reusable Medical Device Champions in designated Reusable Medical Device areas train and validates end user competency.

The Sterile Processing Service Trainer conducts audits and checks the Reusable Medical Device binders in the Reusable Medical Device areas for compliance and reports findings to the Quality Executive Council. Compliance will be monitored in Quality Executive Council monthly until six consecutive months of one hundred percent compliance.

### OIG Comments

The OIG recognizes VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016, which was in effect during the time of the events discussed in this report, was rescinded and replaced by VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023, which removed the requirement to develop a separate standard operating procedure if the manufacturer's instructions for use provides clear guidance to SPS staff about RME.

The OIG will review the follow up to this recommendation with respect to the requirements of VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023.

## Recommendation 8

The Carl Vinson VA Medical Center Director ensures that the facility Water Working Group submits critical water system test results to the Veterans Integrated Service Network Sterile Processing Services Management Board, as required, and monitors for compliance.

Concur_X_

Nonconcur___

Target date for completion: Completed

## Director Comments

The Medical Center Director evaluated this recommendation and found no additional reasons for noncompliance. Carl Vinson VA Medical Center critical water system test results are reported to the Veterans Integrated Service Network Sterile Processing Services Management Board and recorded in the committee's minutes with any warranted corrective actions required. The Carl Vinson VA Medical Center has been in full compliance with this recommendation since October 2023 and shown six consecutive months of sustainment. As an identified opportunity for improvement to maintain sustainment, a standard operating procedure has been developed that outlines the procedures for reporting critical water system test results.

## OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

# Glossary

*To go back, press "alt" and "left arrow" keys.*

**administrative investigations board.** "Administrative investigations are a systematic process for gathering evidence and ascertaining facts about matters of significant interest to VA." Administrative investigations are conducted to determine what happened and why it happened so that any individual and systemic deficiencies can be identified and corrected."[62]

**bioburden.** "The number of microorganisms on a contaminated object."[63]

**critical water.** Is water that is extensively treated to ensure microorganisms, inorganic, and organic materials are removed and used for the final rinse or steam generation.[64]

**endoscope.** "An endoscope is a rigid or flexible device consisting of a tube with a light and a lens on the end that is inserted into a body opening or incision, typically used to examine hollow organs inside the body such as the esophagus, stomach, duodenum, colon or rectum, and is also used to take tissue from the body for test. Endoscopes can attach a camera to take color images of the inside of the body or for viewing on a video screen."[65]

**fact-finding review.** Factfinding reviews and AIBs are tools VHA uses to complete a "systematic, thorough and objective analysis of evidence, documented in a manner that clearly conveys the facts, the evidence from which those facts are ascertained and the investigator's conclusions about disputed matters." "a Factfinding may also result in the need to conduct an AIB." Factfindings are not made under oath and typically completed more quickly.[66]

**hepatitis.** "Hepatitis is defined as inflammation of the liver. Viral hepatitis is one of the various forms of hepatitis and refers to infections caused by viruses that affect the liver. Viral hepatitis includes five distinct diseases, caused by five different viruses. The different viruses are each called by a letter name hepatitis A, B, C, D, E."[67]

**reprocessing. "**Reprocessing is all of the steps performed to make a contaminated item reusable or single-patient use device patient-ready; steps may include cleaning, functional testing, repackaging, relabeling, disinfection, or sterilization."[68]

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[62] VHA Directive 0700, *Administrative Investigation Boards and Factfindings*, August 10, 2021.

[63] VHA Directive 1116(2); VHA Directive 1116.

[64] AAMI TIR34:2014/(R) 2017. *Water for the reprocessing of medical devices*, December 12, 2017.

[65] VHA Directive 1116(2); VHA Directive 1116.

[66] VHA Directive 0700.

[67] Johns Hopkins Medicine Health *"Hepatitis B,"* accessed September 6, 2023, 2018, https://www.hopkinsmedicine.org/health/conditions-and-diseases/hepatitis/hepatitis-b.

[68] VHA Directive 1116(2); VHA Directive 1116.

**reusable medical equipment.** (Device or Item). **"**Reusable medical equipment (RME) is equipment intended for repeated use on different patients with appropriate decontamination and other processing between uses."[69]

**simethicone.** "Is a form of silicone found in several over the-counter anti-gas products. Some gastrointestinal (GI) endoscopy practices use simethicone in an effort to improve visualization during endoscopy."[70]

**sterilization.** An act or process used to destroy or eliminate all microbial forms of life.[71]

[69] VHA Directive 1116(2); VHA Directive 1116.

[70] OLYMPUS, Customer Letter—*Use of simethicone and lubricants*, June 29, 2018, accessed June 29, 2022, https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Customer-Letter---Use-of-simethicone-and-lubricants.pdf.

[71] VHA Directive 1116(2); VHA Directive 1116.

# OIG Contact and Staff Acknowledgments

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