



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

VETERANS HEALTH ADMINISTRATION

Deficiencies in Sterile Processing
Services and Decreased Surgical
Volume at the VA Connecticut
Healthcare System

Newington, Connecticut
West Haven, Connecticut



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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection in response to a request from Senator Richard Blumenthal to review issues related to Surgical and Sterile Processing Services (SPS) within the VA Connecticut Healthcare System (system).

Senator Blumenthal's request came after an unannounced survey of the system by The Joint Commission (TJC) in February 2018 and a subsequent site review by the Veterans Health Administration's (VHA's) National Program Office for Sterile Processing (NPOSP) in May 2018. Both the TJC and NPOSP site reviewers found deficiencies in the system's SPS. TJC initially issued the system's West Haven Medical Center (facility) a Preliminary Denial of Accreditation. As a result, system leaders began an immediate reduction in SPS reprocessing of instruments and limited Surgical Services procedures to focus efforts on correcting the SPS deficiencies.

This inspection focused on several aspects of the system's SPS and the facility's Surgical Services:

- Facility implementation of 2018 TJC and NPOSP recommendations
- SPS standard operating procedures (SOP), training, competence, and staffing
- Surgical cancellations and surgical cases outsourced into the community
- Patient safety and undue burden
- Surgical and post-operative infection rates

The OIG team identified additional concerns related to system leaders' decision-making and actions related to TJC and NPOSP recommendations, and how the current infrastructure, specifically aging buildings, may have impacted their remediation decision-making. The OIG also identified a concern related to the system's residency program.

Facility Implementation of 2018 TJC and NPOSP Recommendations

The OIG team reviewed the TJC surveys and recommendations in addition to system leaders' action plans. The OIG confirmed that TJC site reviewers determined that system leaders had met all requirements for improvement and granted full hospital accreditation on September 5, 2018. To ensure sustainment of system leaders' action plans, TJC reviewers completed a follow-up visit on January 3, 2019, which resulted in no findings.

The OIG reviewed the NPOSP site reviewers' recommendations, which included recommendations of SPS staffing increases, development of quality assurance processes, improvements in staff education and documentation, developing and maintaining SOPs

according to manufacturer's instructions for use, reusable medical equipment storage, and SPS workflow. The OIG determined that the facility followed through with addressing deficiencies identified by NPOSP as needing immediate attention to ensure patient safety. However, the OIG found that NPOSP recommendations related to SOPs, training, competency validation, SPS staffing, quality assurance processes, and staff education and documentation had not been completed.¹

System Leaders' Response

A pattern of questionable SPS decisions made by system leaders impeded progress and created a divide between clinical staff and administration. System leaders failed to proactively communicate or share decision-making related to SPS operations, which led to a culture of divisiveness, a lack of trust, and a loss of confidence in system leaders. System leaders formed an SPS Action Group responsible for the SPS remediation efforts; however, the SPS Action Group did not include system staff with either SPS or operating room experience. The lack of staff expertise in the SPS Action Group impacted the timely and accurate completion of SPS SOPs that were needed to validate staff competencies.²

Infrastructure

The facility's infrastructure was consistent with many of VHA's older buildings. Veterans Integrated Service Network (VISN) and system leaders described environmental challenges associated with the facility's aging infrastructure such as problems with heating, ventilation, and air conditioning systems.³ As of February 2, 2019, additional projects impacting SPS and Surgical Services were still pending; these included securing critical water, replacing ceiling

¹ VHA Directive 1116(2), *Sterile Processing Services*, March 23, 2016. Per VHA directive, "[p]roper reprocessing of RME within VA medical facilities necessitates written and accessible facility policy and procedure that mandates, but is not limited to the following: reprocessing RME according to current manufacturer's instructions; reprocessing RME in accordance with additional standards as cited in this Directive; training of personnel involved in RME reprocessing and validation of such training; and a quality assurance program for RME reprocessing."

² VHA Directive 1116 (2). Each instrument or piece of equipment must have a system-approved SOP (consistent with manufacturer's instructions for use) that describes the proper way to process it. Each staff member must demonstrate the ability to properly process the item (competency) in accordance with the SOP. The frequency for demonstrating competency is dictated by the complexity of the cleaning process and number of times the item is used (if used less frequently, competency assessment may be more often).

³ Within the context of this report, infrastructure refers to conditions at the facility and ACC-N that required support activities for operation and maintenance including painting, metal working, carpentry, lead-based paint, electrical, fabric care, heating and cooling systems, and asbestos.

<https://www.fedcenter.gov/assistance/facilitytour/infrastructure/>. (The website was accessed on April 24, 2019.)

tiles, obtaining an automated cart washer, and continued delays in retrofitting a trailer to reprocess sterile instruments.⁴

In addition to the building infrastructure issues, essential Facility Management Services positions that are needed to assist the facility in planning, design, construction, activation, operations, maintenance, and management were vacant. There had not been a permanent Chief of Facility Management Service from 2012 through 2017, and the most recent Chief left in September 2018. System staff indicated that it was difficult to recruit for these positions because engineering is a competitive field, and VA pay scales are not comparable to community pay scales.

SPS SOP, Training, Competence, and Staffing

Facility leaders were unable to provide documentation of training for more than half of SPS staff for the 12 SPS training modules required within 90 days of hire. An SPS annual training plan or in-service training program had not been previously established. In January 2019, the Sterile Processing Service/Reusable Medical Equipment/Infection Prevention (SPS/RME/IP) Director established a method to track employees' training completion.

SPS staff competencies were not up-to-date. System and SPS leaders had not consistently conducted, tracked, or documented competency assessments as required per VHA directive.⁵ System leaders had significantly underestimated system SPS staffing levels needed to support a facility that provided complex surgical procedures.

VISN and system leaders and staff informed the OIG team that SPS staffing shortages and vacancies had been a long-standing problem to include chronic recruiting challenges and maintaining adequate SPS staff. The Associate Director of Patient Care Services and the VISN Quality Management Officer attributed some of the staffing and recruitment challenges to the nation-wide downgrade of the SPS technician's pay scale.

The OIG team learned that the SPS retention challenges were further exacerbated by the physical working conditions in the SPS space. Inadequate SPS staffing levels was the primary contributing factor to the former Chief of SPS and Assistant Chief's inability to maintain administrative and programmatic functions such as the identified deficiencies with SOPs, training, and competencies.

⁴ Within the context of this report, the OIG uses the term critical water to include deionized and reverse osmosis. Per AAMI, critical water will remove inorganic components as well as microorganisms. "Water for the reprocessing of medical devices. The importance of water quality and effective treatment," *Association for Advancement for Medical Instrumentation Standards Technical Information Report*—AAMI eSubscription VA Health Care. AAMI TIR 34: 2014/(R)2017. https://my.aami.org/aamiresources/previewfiles/TIR34_1409_preview.pdf. (The website was accessed on April 10, 2019.)

⁵ The terms deficiency and vulnerability were both used in NPOSP reports. For the purposes of this report, the OIG uses the term deficiency.

Surgical Case Cancellations and Outsourcing

Facility surgical cases were canceled and outsourced to a non-VA hospital due to unaddressed issues in SPS that were identified in the May 2018 NPOSP site review. Between May 13, 2018, and January 31, 2019, 1,975 surgical patients were outsourced to a non-VA hospital.

After the May 2018 NPOSP site review, system leaders determined that SPS staff could not meet the demands of surgery and limited the types and number of surgical cases performed at the facility. System Surgical Services leaders and staff began to transition all ophthalmology cases to Yale New Haven Health System. Surgical schedule limitations were implemented in total joint surgeries, open heart surgeries, and robotic and advanced laparoscopic surgeries, and the number of cystoscopies were reduced.⁶ Later that summer, the ability to schedule surgical cases was dependent upon which SOPs were completed.

In July 2018, the cardiac catheterization lab suspended services due to scheduled remodeling. Prearranged plans were made for cardiac catheterization lab patients to receive services at a non-VA hospital. The cardiac catheterization lab reopened in April 2019.

The OIG reviewed facility surgical cases that were canceled between August 10 and August 13, 2018, due to contamination of two surgical trays. According to the Chief of Surgery, bioburden was found on a routine ear, nose, and throat instrument tray; therefore, Surgical Services leaders decided to implement an “SPS stand down” on a Friday afternoon, August 10, 2018, for the scheduled Monday surgical cases.⁷ The OIG reviewed 10 surgical cases scheduled between August 10–13, and found three cases for otolaryngology (ear, nose, and throat), one for general surgery, one for urology, and five for mental health. The OIG excluded the five cases in mental health as they did not require the use of reusable medical equipment. Of the five remaining operating room cases, two cases were performed prior to the stand down without complications, two were canceled by the patients due to illness, and one case was rescheduled.

⁶ “Robotic surgery is a method to perform surgery using very small tools attached to a robotic arm. The surgeon controls the robotic arm with a computer.” National Institute of Health/U.S. National Library of Medicine. Medline Plus. Medical Encyclopedia. <https://medlineplus.gov/ency/article/007339.htm>. (The website was accessed on April 10, 2019.) A laparoscopy is a type of surgery where a thin tube called a laparoscope into a patient’s abdomen or a woman’s reproductive system. The laparoscope is attached to a camera and sends images to a video monitor. This allows the surgeon to view inside the body without major trauma to the patient. <https://medlineplus.gov/lab-tests/laparoscopy/>. (The website was accessed on April 22, 2019.) A cystoscopy is a type of surgery where a thin lighted tube with a small camera on the end is inserted through the urethra into the bladder. There are two types of cystoscopes: rigid and flexible. <https://medlineplus.gov/ency/article/003903.htm> (The website was accessed on April 22, 2019.)

⁷ Bioburden is the number and type of variable organisms with which an item is contaminated. <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/glossary.html#B> (The website was accessed April 9, 2019.)

In November, an Environmental Service staff member dislodged a sprinkler head while cleaning the ceiling in the operating room causing the rooms to flood. Due to flood remediation, no further surgeries were scheduled or performed until January 28, 2019.

The inability to perform surgical procedures at the facility further impacted other departments such as the diversion of patients from the Emergency Department to non-VA hospitals. There was a significant decline in patient admissions; nursing care units experienced a decrease in census of 50 percent or more, workload was impacted, and nurses expressed being fearful of losing their jobs. Staff also reported a lack of transparency; although there were “issues,” there was no explanation.

Patient Safety and Undue Burden

The OIG found one SPS related adverse clinical event where a patient required additional general anesthesia. The OIG determined that although the patient did not suffer complications related to the anesthesia given, the patient was placed at additional risk.

Patients reported some frustrations to their care providers related to the reduction of the facility’s SPS and Surgical Services. These concerns included not being able to have their procedures performed at the VA, the coordination of post procedure medication and medical equipment, and parking fees incurred at Yale.

Surgical and Post-operative Infection Rates

The OIG reviewed system leaders’ analysis of surgical site infections identified by the facility and actions taken in three surgical specialties (neurosurgery, orthopedic surgery, and vascular surgery) between 2017 and 2018 and found the reviews to be comprehensive and thorough.

The OIG reviewed the electronic health records of 23 patients who developed a surgical site infection in 2018. The OIG determined that although there were concerns that SPS issues may have led to surgical site infections, the patients had other contributory health factors and were considered a higher risk. Because the operating room was closed and SPS reprocessing was limited, the OIG team was unable to fully evaluate the impact of deficient SPS processes on the rate of surgical site infections.

Residency Program

The system’s residency program had an annual resident full-time equivalent of 186 in over 35 specialties, the majority of which were affiliated with Yale. Twenty-four percent of the residents were assigned to surgery. Through interviews with surgeons and a review of committee meeting minutes, the OIG identified concerns that the residency programs were in jeopardy due to the low patient volume, the limited opportunity for residents to provide comprehensive care for patients, and the limited opportunities for comprehensive surgical experience (clinic, hospital, follow-up).

Future Plans

The OIG team participated in a second visit to the system in February 2019 and found that system leaders continued to struggle to keep the SPS and operating rooms functional. The OIG team was informed of the facility's future plans for SPS including the procurement and installation of a mobile sterile processing unit within 15 months, replacement of the operating rooms' heating, ventilation, and air conditioning systems, which entailed the lease of three trailers to continue surgical services, and the initiation and construction of a \$17 million project to build a new SPS department with an estimated completion date between three to five years.

The OIG made two recommendations to the VISN related to oversight of timely completion of the OIG's recommendations and hiring actions. The OIG made nine recommendations to the System Director related to inclusion of operating room, surgery, and SPS clinical leaders in the SPS remediation efforts; development and implementation of an action plan to establish communication, foster collaboration, and restore staff trust in system leaders; oversight for the timely completion of pending projects impacting SPS and Surgical Services; the development, review, and revision of SOPs and a sustainable process to maintain SOPs; SPS staff training and competencies; maintenance of an SPS staffing plan; evaluation of the readiness of supplies and equipment prior to anesthetizing a patient; evaluation and reporting of the impact on and identified needs of the residency programs; and collaboration between the System Director and the VISN 1 Director.

The VISN and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes E and F, pages 42–54). The OIG will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.



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Abbreviations

ACC-N	Ambulatory Care Center-Newington, CT
ADPCS	Associate Director Patient Care Services
ASA	American Society of Anesthesiologists
CDC	Center for Disease Control and Prevention
EHR	electronic health record
FTE	full-time employee equivalent
HVAC	heating, ventilation, and air conditioning
IFU	instructions for use
NPOSP	National Program Office Sterile Processing
OIG	Office of Inspector General
OR	operating room
RME	reusable medical equipment
SOP	standard operating procedure
SPS	Sterile Processing Service
TJC	The Joint Commission
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a request from Senator Richard Blumenthal to review Surgical and Sterile Processing Services (SPS) within the VA Connecticut Healthcare System (system).⁸

Background

The system, part of Veterans Integrated Service Network (VISN) 1, is composed of a medical center in West Haven (facility), an ambulatory care center in Newington (ACC-N), six community based outpatient clinics, and four Vet Centers.⁹ In 2018, the system served 58,687 patients and had a total of 191 hospital operating beds, including 119 inpatient, 32 domiciliary, and 40 community living center beds. The facility's surgery complexity designation is complex, meaning that it requires the highest level of facility infrastructure and performs the most complex surgical procedures.¹⁰

The system is affiliated with the Yale University School of Medicine and the University of Connecticut Schools of Medicine and Dentistry. A VA Nursing Academy is based at the facility in partnership with the Fairfield University School of Nursing.¹¹

The Joint Commission

The Joint Commission (TJC) is an internationally accepted external accreditation body that has accredited VA medical facilities for over 35 years.¹² Accreditation by the TJC provides

⁸ VHA Directive 1116(2), *Sterile Processing Services*, March 23, 2016. Sterile is defined as being completely devoid of all-living microorganisms. Sterile Processing Services is the department in a facility responsible for decontamination, high-level disinfection, and/or sterilization of critical and semi-critical reusable medical equipment and instruments.

⁹ The facility provides primary, secondary, and tertiary care; long-term care programs; and behavioral health services. The ACC-N provides primary, specialty, and urgent care. Community based outpatient clinics are located in Danbury, John J. McGuirk, Stamford, Waterbury, Willimantic, and Winsted, CT. Vet Centers are located in Danbury, Hartford, Norwich, and New Haven, CT.

¹⁰ VHA assigns all its inpatient medical centers an operative complexity (standard, intermediate, or complex) and provides guidance regarding infrastructure requirements. VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This directive was rescinded and replaced by VHA Directive 1220, *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019. The 2019 directive substantially changed the complexity level designation. The 2019 changes do not affect the findings discussed in this report.)

¹¹ VA Connecticut Healthcare System Internet Reference. <https://www.connecticut.va.gov/about/index.asp>. (The website was accessed on May 16, 2019.)

¹² VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017. Accreditation is the determination by an accrediting body that a health care organization complies with applicable standards.

recognition that a healthcare organization meets certain quality and safety standards, as well as compliance with health care quality standards of public and private payors. Accreditation is an ongoing process where healthcare facility leaders must demonstrate provision of safe, high quality care, as determined by compliance with TJC standards, National Patient Safety Goals' recommendations, and performance measure requirements.¹³ TJC surveyors conduct an unannounced site visit (survey) to accredited health care organizations a minimum of every 39 months to evaluate compliance with health care standards.¹⁴

Sterile Processing Services

According to Veterans Health Administration (VHA), SPS has the primary responsibility in facilities to decontaminate and/or sterilize critical and semi-critical reusable medical equipment (RME).¹⁵ In its guideline, the Centers for Disease Control and Prevention suggests failure to properly disinfect or sterilize equipment carries significant risk for person-to-person transmission of infectious diseases (such as human immunodeficiency viruses [HIV] and hepatitis), surgical site infections, and healthcare acquired infections.¹⁶ VHA defines that, "SPS supports the medical facility by ensuring a continuous flow of processed RME to all points of use." In addition, SPS leaders are responsible for overseeing the reprocessing, maintenance, and storage of RME.¹⁷

The VHA National Program Office for Sterile Processing (NPOSP) is a distinct program office under the VHA Deputy Under Secretary for Health for Operations and Management. The NPOSP is "responsible for establishing policy regarding reprocessing of critical and semi-critical RME."¹⁸ VHA directive outlines NPOSP responsibilities.¹⁹

¹³ National Patient Safety Goals are developed by TJC to improve patient safety by focusing on problems in health care safety and how to resolve them.

https://www.jointcommission.org/assets/1/6/2018_HAP_NPSG_goals_final.pdf. (The website was accessed March 27, 2019.) VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017.

¹⁴ Joint Commission website FAQs. <https://www.jointcommission.org/about/jointcommissionfaqs.aspx> (The website was accessed on February 5, 2018.)

¹⁵ VHA Directive 1116(2); Decontaminate is to remove dirty or dangerous substances (such as radioactive material) from a person, place, or thing. <https://www.merriam-webster.com/dictionary/decontaminate>. (The website was accessed on April 8, 2019.)

¹⁶ Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008. Last updated May 2019. <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf> (The website was accessed on August 6, 2019.)

¹⁷ VHA Directive 1116(2).

¹⁸ VHA Directive 1116(2).

¹⁹ VHA Directive 1116(2).

- Oversight of RME to ensure reprocessing requirements
- Guidance for standardization of equipment types
- Definitions of standards that apply to sterile processing wherever high-level disinfection occurs in a facility²⁰
- Specific requirements for environmental controls

Each VISN Director is responsible for appointing a VISN SPS Management Board that oversees reprocessing at all facilities within the VISN and ensuring that training is provided and a quality assurance program is in place. The VISN SPS Management Board must confirm that reprocessing and other SPS functions occur to exacting standards—that is, the current manufacturer’s instructions for use (IFU).²¹

Within individual medical facilities, the director is responsible for ensuring compliance with the overall SPS policies and procedures related to the sterilization of instruments and equipment. Organizationally, SPS is aligned under the Associate Director Patient Care Services (ADPCS) who has the responsibility for providing the oversight, organizational responsibility, and leadership of local SPS operations.²²

Congressional Request for Review

In May 2018, the NPOSP conducted a site review after the TJC cited the system in February for SPS deficiencies NPOSP also identified deficiencies (see appendix B) that resulted in patients being sent into the community (Yale New Haven Health System [Yale]) for eye surgeries and curtailment of other surgical services (see appendix A for a sequence of events).²³ In August, the finding of bioburden and stains on a surgical tray resulted in a three-day shut down of the system’s operating room. Although the operating room reopened after the three days, system leaders limited reprocessing to 15 trays per day, which severely limited the number of surgeries that could be performed.

²⁰ VHA Directive 1116(2). “High level disinfection is a process that uses a sterilant for a shorter contact time than that used for sterilization and kills all microbial organisms but not necessarily large numbers of bacterial spores.”

²¹ VHA Directive 1116(2).

²² VHA Directive 1116(2).

²³ The Yale New Haven Health System, an integrated delivery system that includes the flagship hospital-the Yale-New Haven Hospital (YNHH), Bridgeport Hospital, Greenwich Hospital, and their affiliated organizations. For the purposes of this report, the OIG will refer to any hospital within the Yale New Haven Health System as Yale. <https://medicine.yale.edu/about/institutions.aspx>. (The website was accessed March 24, 2019.)

In late 2018, Senator Blumenthal contacted the OIG and requested that the OIG review several aspects of the facility's SPS and Surgical Services:²⁴

- Facility implementation of 2018 TJC and NPOSP recommendations (section 1)
- SPS standard operating procedures (SOP), training, competence, and staffing (section 4)
- Surgical cancellations and surgical cases outsourced into the community (section 5)
- Patient safety and undue burden (section 6)
- Surgical and post-operative infection rates (section 7)²⁵

The OIG identified other potential deficiencies related to system leaders' response to TJC and NPOSP recommendations (section 2) and how the current infrastructure, specifically aging buildings, may have impacted their remediation decision-making (section 3). The OIG also identified a concern related to the system's residency program (section 8).

OIG leaders and inspectors met with system leaders in 2019 to discuss the system's long-term solutions (see appendixes C and D).

Scope and Methodology

The OIG initiated an inspection of the system on October 3, 2018, and conducted site visits December 10–14, 2018 and February 1, 2019, with the second visit being at the invitation of VHA leadership.

The OIG team conducted 64 interviews that included VHA leaders from the VA National Surgery Office and NPOSP; VISN, system, and facility leaders; key facility medical and surgical clinicians, technologists, managers, and staff; as well as SPS managers and staff.

The OIG team reviewed relevant documents including VA/VHA, VISN, and system directives, handbooks, policies, and SOPs related to SPS and system action plans. The OIG also reviewed guidelines, recommendations, and reports from the Association for Professionals in Infection Control and Epidemiology, Centers for Disease Control and Prevention (CDC), TJC, VA National Surgery Office, and NPOSP, and pertinent medical and industry literature.

In addition, the OIG team reviewed relevant committee meeting minutes, SPS employee training and competency records, SPS staffing rosters and organizational charts from August 2015 through January 30, 2019, and a tracking tool developed by Surgical Services leaders to

²⁴ On September 18, 2018, OHI leadership accepted a hotline from Senator Richard Blumenthal's office regarding the VA Connecticut Healthcare System. This was followed by a formal Congressional complaint (2019-00075-CR-0002) on October 3, 2018.

²⁵ The OIG determined that SPS processes were also provided at the ACC-N and therefore included ACC-N in the review.

ensure the coordination of care for all outsourced surgical patients. The OIG team reviewed electronic healthcare records (EHRs) of patients who had a surgical site infection in 2018, and one patient who had an adverse event.

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).

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.

Inspection Results

1. Facility Implementation of 2018 TJC and NPOSP Recommendations

TJC Survey

During the week of February 13, 2018, TJC conducted an unannounced survey of the system's hospital, behavioral health, and home care programs. While on-site, the TJC surveyors issued eight requirements for improvement specific to SPS. TJC issued a Preliminary Denial of Accreditation.²⁶

On May 4, TJC surveyors conducted a follow-up unannounced on-site review. Again, the system was given a Preliminary Denial of Accreditation. System leaders appealed TJC's determination, received help from NPOSP and an outside consultant, and developed an action plan.

On September 5, TJC determined that system leaders had met all requirements for improvements and granted the system full accreditation. To ensure sustainment of system leaders' action plans, TJC surveyors completed a follow-up visit on January 3, 2019, which resulted in no findings.

NPOSP Site Visit

During the week of May 8, 2018, NPOSP reviewers conducted an unannounced "For Cause" site review related to the TJC survey conducted February 13–16, 2018, at the request of the former VHA Director of External Accreditation Programs. While on-site, NPOSP reviewers conducted a comprehensive inspection of the system's RME and SPS programs, in addition to the "For Cause" site review. The NPOSP reviewers' recommendations included SPS staffing increases, development of quality assurance processes, improvements in staff education and documentation, developing and maintaining SOPs according to manufacturer's IFUs, RME storage, and SPS workflow. Additionally, NPOSP reviewers identified vulnerabilities (nonconformities) that were to be addressed immediately to ensure patient safety. (See appendix B.)

Following the NPOSP "For Cause" site review, system leaders developed an action plan to address the review findings. System leaders began an immediate reduction in SPS reprocessing

²⁶ According to TJC, a "Preliminary Denial of Accreditation is recommended when there is justification to deny accreditation to a health care organization as evidenced by one or more of the following: an immediate threat to health or safety to patients or the public; submission of falsified documents or misrepresented information; lack of a required license or similar issue at the time of survey; failure to resolve the requirements of an Accreditation with Follow-up Survey status; or significant noncompliance with Joint Commission standards." https://www.jointcommission.org/facts_about_accreditation_and_certification_decisions/. (The website was accessed on February 7, 2019.)

of instruments and limited Surgical Services procedures to focus efforts on correcting the NPOSP findings.

At the time of its December 2018 visit, the OIG determined that the system addressed the immediate nonconformities, including RME storage and revision of the SPS workflow. However, recommendations related to SPS staffing, quality assurance processes, staff education and documentation, and SOPs had not been completed. These topics are addressed within this report.

2. System Leaders' Response

The OIG reviewed the actions that system leaders took in 2018 to improve SPS deficiencies. The OIG found a pattern of questionable SPS decisions made by system leaders that impeded progress and created a divide between clinical staff and administration. OIG inspectors were told that system leaders showed a lack of proactive communication and shared decision-making related to SPS operations that led to a culture of divisiveness, a lack of trust, and a loss of confidence among system staff. System leaders did not include staff with either SPS or operating room experience in the SPS Action Group. The lack of staff expertise in the SPS Action Group had an impact on the timely and accurate completion of SOPs that were needed to validate staff competencies.²⁷

The OIG team conducted interviews that included VISN and system leaders, managers, service chiefs, physicians, nurses, and technicians from a wide array of disciplines and services.²⁸ During the course of those interviews, more than half expressed varying levels of concern, frustration, and disheartenment regarding the decisions made and actions taken by system leaders, specifically the System Director (Director) and ADPCS during the SPS remediation efforts. System staff reported that decisions and actions taken by system leaders, namely the Director and ADPCS, impeded the timely resolution of issues, placed vital programs at risk, created a climate of fear and mistrust, and formed a divide between clinical and administrative services. During interviews, common themes emerged; the most prevalent were the lack of subject matter expertise, engagement and collaboration, shared decision-making, and communication and transparency. Equally apparent during the interviews was the absence of

²⁷ Each instrument or piece of equipment must have a system-approved SOP (consistent with manufacturer's instructions for use) that describes the proper way to process it. Each staff member must demonstrate the ability to properly process the item (competency) in accordance with the SOP. The frequency for demonstrating competency is dictated by the complexity of the cleaning process and number of times the item is used (if used less frequently, competency assessment may be more often).

²⁸ For the purposes of this report, the OIG uses the term system leaders to refer to individuals in executive leadership positions to include the Director, ADPCS, and Associate Director. The term system staff is used to identify all other employees interviewed (service chiefs, managers, surgeons, nurses, technicians, and other front-line staff). The OIG team interviewed some individuals more than once.

positive feedback regarding system leaders' actions, communications, and effectiveness in resolving the SPS deficiencies reported to the OIG team.

Associate Director Patient Care Services and SPS Action Group

System leaders reported that following the TJC's Preliminary Denial of Accreditation and subsequent NPOSP site visit in May 2018, they determined SPS challenges were more complex and widespread than originally thought. The Director appointed the ADPCS to lead remediation efforts.²⁹

Given this charge, the ADPCS reported forming an SPS Action Group. The group was led by the ADPCS, who had been in the current position for two years and whose previous experience included working in several geriatric care programs.³⁰ Additional team members selected for the group included the Director of Home Based Primary Care Services, the Hospital Epidemiologist, the Chief of Hospital Education, and the Administrative Officer for Geriatrics and Extended Care. In August 2018, two additional staff were added to the team to provide program support.

The OIG interviewed the ADPCS on December 10 and 13, 2018. The ADPCS stated on both occasions being new and not an SPS subject matter expert. The ADPCS explained that after spending the week with the NPOSP reviewers, "I decided to take that deep dive into SPS and bring it down to bare bones . . . to ensure they were providing safe care to patients." The ADPCS further added, "[b]ecause I am not the subject matter expert, and there wasn't anyone that could provide me with that information . . . the best option was to cut back on critical procedures." When the OIG team questioned the ADPCS about pre-existing SPS capacity issues, the ADPCS reminded the team about being new and not knowing if there was or was not an SPS capacity issue because, "I'm not a subject matter expert." The ADPCS stated being aware the operating room (OR) staff offered to help with the revision of SPS SOPs and competencies, but did not accept their help because they were not trained on all equipment. The OIG team asked if the SPS Action Group kept meeting minutes documenting the key decisions made; the ADPCS said that minutes were taken for some but not all meetings. During interviews, the ADPCS stated having learned a lot about SPS throughout this process.

The OIG team requested a copy of the SPS Action Group's charter or charge letter, meeting minutes and attendance records; however, system leaders did not have documentation regarding the formation of the group, the purpose or charge of the group, or the authority given to the group, nor were system leaders able to provide any SPS Action Group meeting minutes. System

²⁹ VHA Directive 1116(2). The ADPCS is responsible for "[p]roviding oversight, organizational responsibility, and leadership of the local SPS operations" among other duties.

³⁰ The ADPCS reported working in the system for 28 years and serving as the ADPCS for the past two years. Prior to this position, the ADPCS worked in geriatric programs including the Community Living Center, Home Based Primary Care, and served as a care line manager in the Geriatric Extended Care services for 10 to 12 years.

leaders provided several tracking sheets in place of the meeting minutes which were departmental status updates that had been presented to the SPS Action Group.

Lack of Subject Matter Expertise

System staff reported that the individuals selected to participate in the SPS Action Group—that subsequently made unilateral decisions about SPS operations—did not have experience or a working knowledge of SPS or the OR.³¹ Therefore, the group did not have full insight into the needs and limitations of a surgical service. System staff reported the ADPCS refused offers of assistance from Surgical Services leaders, service chiefs, surgeons, operating room nurse managers, operating room nurses, and surgical and SPS technicians to develop SOPs, which not only impeded progress, but created silos and lowered staff morale.³²

System staff clarified how the SPS Action Group’s inexperience impeded progress:

- Lack of critical SPS process steps
- Unrevised SOPs that lacked critical steps
- Difficulty distinguishing between the need to make a minor versus a major SOP revision
- Failure to prioritize SOP revisions thereby impacting the type of surgery that could be performed
- Limited recognition of the full impact SPS limitations had on Surgical Services providers, anesthesiologists, nurses, and residents

Lack of Transparency and Communication

The lack of transparency and communication by system leaders and the SPS Action Group were additional concerns repeatedly identified by system staff, including those working closely with the SPS Action Group. Staff were not informed of the “big picture” or the scope of the TJC and NPOSP findings that resulted in the significant reduction of SPS operations. System staff reported that communication with the SPS Action Group was one-way; system staff and services did not receive information from the group but were expected to report to the group in a designated time slot. Staff reported their employees read about the system’s problems in the newspaper and worried about job security. The general consensus was that system leaders did not adequately convey pertinent SPS related information to staff. Although the Director held an Employee Town Hall meeting during the SPS remediation efforts, a staff member reported that

³¹ The terms SPS Action Group, Incident Command Center, and SPS Work Group were used interchangeably by system leaders and staff. For the purposes of this report, the OIG will use the term SPS Action Group.

³² System staff described the SPS Action Group’s unilateral decision-making and actions in various ways such as, “closing ranks,” “bunker mentality,” “pulling in the people you trust,” “cliques,” “silos,” “absolute power,” “disconnect between the leadership and what their vision is and the doctors in the trenches,” “molasses...no sense of urgency from administration,” and “risk aversion.”

the event was announced two days in advance and “was not publicized.” One staff member reported that the Director gave a “slick slide show” of accomplishments but failed to comment on any SPS related issues or the impact on Surgical Services until questioned directly. Another staff member said the Director did not discuss SPS information at the Town Hall meeting, and stated, “Why aren’t we talking about the elephant in the room?” System staff reported the lack of communication from system leaders, a culture of distrust, and uncertainty negatively impacted staff morale.

The Director, Associate Director, and the ADPCS reported regularly communicating with system employees through Employee Town Halls and service section meetings, emails, and presentations. The ADPCS provided the OIG team with an “example communication” titled *Leadership SPS Update Presentation*. The presentation consisted of three slides that introduced the SPS VHA Directive 1116 (2), listed operational items under SPS (staffing, equipment, storage), and a list of what system staff should do (no storage on the floor). The presentation did not include information regarding why SPS services were limited, what deficiencies were found, or what corrective actions were taken.

3. Infrastructure

Consistent with many of VHA’s older buildings, the main hospital infrastructure at the facility was built in 1955 and had renovations in 1999. In 2018, the Government Accountability Office found that “[o]lder VHA facilities have challenges maintaining environmental parameters such as airflow, humidity, and temperatures.”³³

VISN and other system leaders described environmental challenges associated with the facility’s aging infrastructure such as problems with heating, ventilation, and air conditioning (HVAC). The Director told the OIG team about being concerned with the facility’s “failing infrastructure since [the Director’s] first week” at the system.³⁴ The Director stated having submitted two

³³ United States Government Accountability Office, GAO-18-474. Report to the Chairman, Committee on Veterans’ Affairs, House of Representatives. *VA HEALTHCARE. Improved Oversight Needed for Reusable Medical Equipment*, August 2018. VHA guidelines state that Facility Management Services are responsible for maintaining “VHA-owned infrastructure with an average building age of over 55 years.” VHA Center for Engineering and Occupation Safety and Health. Healthcare Engineering Guidebook. http://vaww.ceosh.med.va.gov/01HP/02HP_Guidebooks/03_Collections/04HP_HealthcareEngineering/HCE2018.pdf. (The website was accessed on April 12, 2019.)

³⁴ Within the context of this report, infrastructure refers to conditions at the facility and ACC-N that required support activities for operation and maintenance including painting, metal working, carpentry, lead-based paint, electrical, fabric care, heating and cooling systems, and asbestos. <https://www.fedcenter.gov/assistance/facilitytour/infrastructure/>. (The website was accessed on April 24, 2019.)

requests for funding—one for a new hospital and one for a new tower—that had both been denied.³⁵

During an OIG interview, the Chief of Staff explained that when the main hospital at the facility was built, interior bricks were used on the outside of the building as opposed to exterior bricks, and the bricks began to fall off. System leaders determined the solution was to put “a skin” on the building with space between the building and the space. A skin was placed, after two attempts; however, the space left between the building and exterior skin allowed animals access into this space and made repairs difficult.

In addition, SPS is in the basement, and the floor lies across the top of steam conduits from the power plant. The OIG was told that the floor temperature in SPS during the summer months could reach over 90 degrees.

Infrastructure Emergencies

Issues that exacerbated infrastructure problems included frequent emergencies that continued to add to the overall requirements for solutions and utilization of resources. During interviews, Facility Management Service staff told the OIG team that many of the planned projects were completed after hours and on weekends because they were frequently removed from planned projects to address infrastructure emergencies (see table 1).

³⁵ The Director reported an initial request for funding a new building was denied, and a second request for funding for the construction of a separate state of the art tower (with individual floors for pharmacy, surgery, SPS, and lab) with its own HVAC system was also denied.

Table 1. Examples of System Infrastructure Emergencies

Condition	Date	Cause	Effect	Resolution
Newington Flood	November 24, 2017	Leak in pipe	Flooded Building 2 (floors five to ground level)	Professional remediation, asbestos abatement, mold abatement, replaced floors, walls, and ceilings
West Haven Flood	January 7, 2018	Sprinkler pipe froze and broke	Flooded Building 5 (floors three to ground level)	Professional remediation, asbestos abatement, replaced floors, walls, and ceilings.
Chiller Plant Heat Exchanger	July 26	Unknown	Building cannot be cooled down in late afternoon	Replaced for approximately \$260,000
Pump in boiler plant failed and Chiller Plant shut down on Sept.25 at 2:00 a.m.	September 25	Main feed water pump bearing failed	No steam for facility	Boiler plant taken offline, hand fed water to boilers, replaced failed bearings. (Boiler main feed pumps past life expectation, short-term repairs as needed until project replacement is done.)
West Haven OR Flood	November 3	Sprinkler head in OR damaged while cleaning	Surgical Services not operational	Professional remediation, mold abatement, replaced floors, walls, and ceilings

Source: System Environment of Care, Infection Prevention and Control, and OR Management Meeting Minutes

As of February 2, 2019, additional projects impacting SPS and Surgical Services were still pending completion, as described below.

Chronic Problems in SPS

Shortage of Critical Water

In the SPS design guide, VHA states that “[t]he quality of the water used in SPS equipment vastly affects the end result of RME reprocessing.”³⁶ While tap water may be used in some phases of reprocessing, water that has been “extensively treated” (critical water) should be used in the final rinse of instruments to remove inorganic components as well as microorganisms.³⁷

In the 2016 report to the facility, NPOSP reviewers recommended that system leaders design a plan to “plumb” critical water to the SPS washer/disinfector for final rinses of instruments. An interviewee indicated to the OIG that funding for design was obtained from NPOSP in 2016 for a critical water system; however, contracting would not fund the construction. System leaders were unable to provide information regarding the denial of construction funding.³⁸ In March 2017, the VISN Quality Management Officer noted that deionized (critical) water was only available in small quantities, and informed system leaders the “department [SPS] needed a ready source of purified (i.e., deionized water) to comply with manufacturer’s instructions for use.”

An interviewee indicated, and the August 3, 2018, RME meeting minutes confirmed, that SPS purchased “jugs” of critical water, and the final rinse of instruments was performed manually. The manual rinse process prohibited the reprocessing of instruments needed for more complex neurosurgery or orthopedic procedures. During their 2018 visit, the OIG team members noted the system leaders had not acted on the “plumbing” recommendation. At that time, NPOSP staff and system leaders informed the OIG team that until critical water was available, Surgical Services would not be able to perform more complex cases.

³⁶ VA, *P.G. 18-12: Sterile Processing Services and Logistics Service, Space Planning Criteria, Equipment Guidelist, Design Guide*. October 1, 2015. <https://www.wbdg.org/FFC/VA/VADEGUID/spsls.pdf>. (The website was accessed on October 22, 2018.) The guide categorizes water into four groups: tap water or potable, softened, deionized, and reverse osmosis. “Deionized water is used for final rinses and the steam sterilization process. This decreases mineral deposits on instrumentation and helps maintain the efficiency of the sterilization equipment.” Reverse osmosis “water is highly processed to remove microorganisms, inorganic material, and organic material from the water.” *Deionized* refers to the removal of ions (an atom or group of atoms that carries a positive or negative electric charge). <https://www.merriam-webster.com/dictionary/ions>. (The website was accessed on April 8, 2019.) *Reverse osmosis* is the movement of fresh water through a semipermeable membrane when pressure is applied to a solution (such as seawater) on one side of it. <https://www.merriam-webster.com/dictionary/reverse%20osmosis>. (The website was accessed on April 8, 2019.)

³⁷ Within the context of this report, the OIG uses the term critical water to include deionized and reverse osmosis. Per AAMI, critical water will remove inorganic components as well as microorganisms. “Water for the reprocessing of medical devices. The importance of water quality and effective treatment,” *Association for Advancement for Medical Instrumentation Standards Technical Information Report—AAMI eSubscription VA Health Care*. AAMI TIR 34: 2014/(R)2017. https://my.aami.org/aamiresources/previewfiles/TIR34_1409_preview.pdf. (The website was accessed on April 10, 2019.)

³⁸ The system’s Associate Director estimated the installation of a deionized water system to be 12 million dollars.

In February 2019, system leaders informed the OIG a critical water system for final rinsing of instruments was installed. However, the critical water system was considered to be temporary until the construction of a new SPS.

Missing Ceiling Tiles

Decontamination, scope processing, preparation, assembly, and sterilization areas in SPS must have continuous ceiling tiles.³⁹ In the May 2018 NPOSP “For Cause” review, NPOSP reviewers identified areas where ceiling tiles did not meet SPS design guidelines. On December 11, 2018, the OIG toured the facility SPS and identified an area where two sterilizers were located that did not have a continuous ceiling. The OIG informed the system leaders. As of March 14, 2019, this project had not been completed.

Lack of Automated Cart Washer

In 2016, the NPOSP recommended the installation of an automatic cart washer. The OIG was told by an interviewee that SPS staff manually washed carts because there was not an automated cart washer at the facility. Soiled case carts must be cleaned after each use.⁴⁰

In January 2016 RME meeting minutes, it was reported that an automated cart washer was funded for design but not construction. In the July RME meeting minutes, it was reported that NPOSP reviewers recommended the purchase and installation of an SPS automated cart washer to improve the process of manually disinfecting all carts that entered the decontamination area, but the automated cart washer project was on hold due to budgeting concerns.⁴¹ In addition, the July meeting minutes noted a discussion that the lack of an automated cart washer had been an Occupational Safety and Health Administration and TJC finding in the past. In the September RME meeting minutes, it was noted the former Chief of SPS submitted a request for the cart washer project to the NPOSP although if approved, local funding would still be needed for construction. October RME meeting minutes reflected that Facility Management Service staff was submitting a request for the construction funding. However, the project continued to be open without further updates through July 2017. From August 2017 until June 2018, there was no record of any RME meetings. As of July 2018, the purchase of an automated cart washer was in contracting for the facility, and a design for the ACC-N was funded and a contract for design was awarded.

³⁹ VA, Sterile Processing Services and Logistics Service Design Guide.

⁴⁰ VHA Directive 1116(2).

⁴¹ VA, Sterile Processing Services and Logistics Service Design Guide. An automated cart washer is provides a means to clean case carts, as well as ridged instrument containers.

Interviewees told the OIG that it was difficult to install the automated cart washer due to space limitations and that this concern had been discussed since 2003. Facility Management Service staff reported at an SPS/OR meeting in November 2018 that the facility and the ACC-N would both require an additional investigation/survey of existing utility and infrastructure systems and alterations necessary for the installation of a cart washing system within the SPS department.⁴²

While on-site in February 2019, the OIG team found the facility cart washer had not yet been installed because it required customization from the vendor to fit in the SPS space.

Delayed Trailer Retrofit

The OIG team was informed during their site visit about a four-year delay in retrofitting a trailer for reprocessing RME. In 2014, system leaders obtained a trailer from another VA facility. The former Chief of SPS worked with Facility Management Services to install the trailer and order the necessary equipment.

In February 2015, system leaders contracted a design for the SPS trailer, and in May, it was determined that asbestos sampling would need to be included in the design. The construction contract was approved in November, and construction began in February 2016. Modifications to the contract were required to oversee asbestos abatement and to remove debris and materials in a crawl space. According to a system project manager, the trailer was “substantially complete” in June 2016.

In July, NPOSP reviewers became involved in the project during their visit to the facility. NPOSP reviewers determined the trailer was “new construction” and identified inadequate work and people flow issues in the SPS trailer that could lead to cross contamination issues. The trailer was not allowed to open as constructed. On November 1, the request for proposal for the recommended changes was sent to the contractor. However, in December, RME meeting minutes reflected a delay in the release of funding.

In January 2017, the SPS Directive was revisited to determine system leaders’ ability to meet the requirements for the project. In April 2017, system leaders continued to wait on contracting approval of the architectural engineering modifications. An approval for prior year’s funding was approved in June and July. The updated design drawings were received in September, and the new construction package was submitted to contracting in October along with a request for the release of prior year funds for the modification. By November, system leaders had received several requests for improvement and returned these to the architectural engineering firm for

⁴² The installation of the cart washer within SPS required alterations to the existing plan of the interior spaces, and supplied with proper utilities per manufacturer’s specifications. Additionally, existing HVAC systems required investigating to remove humidity and establish proper temperature controls for cart washer and surrounding areas it would be affecting.

incorporation. A cost proposal was provided by the contractor to system leaders in December, was submitted for negotiations, and funding was again requested.

In March 2018, construction modifications were issued, funding was released in June, and construction began. In June, NPOSP made an additional visit which resulted in a project stop work order. In July, the stop work order was lifted to perform work outside the trailer itself; however, the NPOSP visit resulted in requirements to re-work the trailer design and flow. A change in the purpose of the trailer was also made to limit reprocessing to dental and outpatient clinic instruments. Between September and December, a modified trailer layout was developed, and design and contracts were submitted to VA. The OIG was told by Facility Management Services staff that they were planning a three-month construction period in the spring of 2019.

System Facility Management Service Staffing

The OIG determined that there were vacancies in key Facility Management Services positions. Staff told the OIG that there had not been a permanent Facility Management Service Chief from 2012 through 2017, and the most recent Facility Management Service Chief left in September 2018.

Facility Management Service staff are key to maintaining a safe environment for patients, staff, and visitors.⁴³ A safe environment includes maintaining environmental controls to ensure the sterility of RME, such as air flow, air exchanges, humidity, and temperature.⁴⁴ Facility Management Service staff serve the facility through processes of planning, design, construction, activation, operations, maintenance, and management.

Although there had been recruiting activities, system staff indicated that it was difficult to recruit for the position because engineering is a competitive field, and VA pay scales are not comparable to community pay scales. An interviewee told the OIG that there was not a lot of opportunity to train and mentor new employees due to system demands.

4. SPS SOPs, Training, Competency, and Staffing

Per VHA directive, “[p]roper reprocessing of RME within VA medical facilities necessitates written and accessible facility policy and procedure that mandates, but is not limited to the following: reprocessing RME according to current manufacturer’s instructions; reprocessing RME in accordance with additional standards as cited in this directive; training of personnel

⁴³ Burmahl, B. Health Facilities Management. *Facility-related operations play bigger role in patient safety*. December 2, 2015. <https://www.hfm magazine.com/articles/1829-facility-related-operations-play-bigger-role-in-patient-safety>. (The website was accessed on March 5, 2019.)

⁴⁴ VHA Directive 1116(2).

involved in RME reprocessing and validation of such training; and a quality assurance program for RME reprocessing.”⁴⁵

SOPs

SOPs are step-by-step written instructions on how to perform specific tasks or procedures. VHA policy requires SOPs for reprocessing RME to be written according to manufacturer’s IFUs.⁴⁶ According to CDC, “health-care policies must identify, primarily on the basis of the items’ intended use, whether cleaning, disinfection, or sterilization is indicated.”⁴⁷ While the Director is ultimately responsible for ensuring that medical device-specific standards and systematic RME processes are developed, the ADPCS is responsible for “[p]roviding oversight, organizational responsibility, and leaders of the local SPS operations. The day-to-day operational oversight for SPS may be assigned to a designee; however, SPS will directly report to the ADPCS.”⁴⁸

In December 2018, the OIG determined that system staff were continuing to revise outdated SOPs according to manufacturers’ IFUs. In May 2018, NPOSP reviewers found that SOPs and competencies related to critical and semi-critical RMEs were outdated throughout the system.⁴⁹ NPOSP reviewers recommended that the review of SOPs be a collaborative effort by the RME coordinator, infection control staff, RME champions, and other end-user representatives.

Per VHA policy, the ADPCS ensures the Chief of SPS implements SOPs on how to reprocess each RME based upon manufacturer’s IFUs.⁵⁰

The SOPs must be kept current, reviewed at least every three years, and updated when processes or manufacturer’s IFUs change.⁵¹

The SPS Action Group, led by the ADPCS, developed a spreadsheet to identify all RME SOPs; determine how often the SOP required review; and track the date the SOP was last reviewed, the next due date, the responsible service, and the status of the SOP review. The status column indicated if the SOPs had been completely validated, cleared for competency validation, under revision, revisited, pending signatures, and if competency validation had been initiated.

⁴⁵ VHA Directive 1116(2).

⁴⁶ VHA Directive 1116(2).

⁴⁷ CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Last updated May 2019. <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>. (The website was accessed on August 6, 2019.)

⁴⁸ VHA Directive 1116(2).

⁴⁹ VHA Directive 1116(2). RME includes instruments or objects introduced directly into the bloodstream or other normally sterile body areas (critical items) and those that come in contact with non-intact skin or mucous membranes (semi-critical items).

⁵⁰ VHA Directive 1116(2).

⁵¹ VHA Directive 1116(2). This is one method by which SPS Chiefs can ensure a facility’s reprocessing of critical and semi-critical RME is performed with high reliability.

The SPS Action Group initially identified 248 SOPs; however, after removing those that were retired or expired, there were 200 SOPs to be reviewed. This was congruent with the information provided to the OIG team in an interview. The ADPCS could not provide a target date for the completion of all 200 SOPs and stated it was a “moving target,” and the timeline was “crude.”

Training

Per VHA policy, the ADPCS is responsible for overseeing the development, implementation, and management of SPS training programs, while the Chief of SPS is responsible for ensuring all SPS employees are properly trained and competency validated. The Chief of SPS is responsible for confirming that SPS personnel receive training on each RME’s manufacturer based SOP prior to performing sterilization tasks. Additionally, the Chief of SPS is required to develop and implement a continuing education and development program to include an orientation program for new employees, Level 1 training, and recurring on-the-job training for all SPS staff.⁵² The OIG determined that training records for SPS staff were incomplete.

Level 1 Training and Annual Training Plan

The OIG determined that in 12 of the 23 (52 percent) SPS staff records reviewed, staff had not completed the 12 training modules needed to obtain Level 1 certification.⁵³ VHA policy requires SPS staff to complete basic SPS Level 1 training within 90 days of hire.⁵⁴

The OIG team was informed that neither an annual training plan, nor a continuing education program had been developed or implemented, as required. The OIG team was told that vendors periodically came to the system to provide in-service training, but there was no calendar to track the training or the attendees.⁵⁵ Although system leaders did not have evidence that an annual training plan or in-service training program was previously established, the OIG confirmed that as of January 2019, the SPS/RME/Infection Prevention Director (hired in November 2018) had established a method to track employees’ training completion.⁵⁶

⁵² VHA Directive 1116(2).

⁵³ The OIG team received a list of SPS staff who reprocessed RME and were employed at the system as of December 10, 2018. The OIG team limited the review to the 23 employees who were hired on or before September 30, 2018, as those employees should have completed their SPS Level 1 training requirements within the required 90 days of hire.

⁵⁴ VHA Directive 1116(2).

⁵⁵ For this report, vendors refer to representatives of companies who sell instrumentation and equipment utilized in SPS and surgery and often provide education (in-service training) to staff.

⁵⁶ The new staffing plan called for an SPS Director as well as a Chief of SPS at West Haven and a Chief of SPS at ACC-N.

Competency

Competency development focuses on the knowledge, skills, and abilities required for an employee to be deemed proficient and able to work independently.⁵⁷ SPS staff must demonstrate competency, and SPS managers must document staff competency for instruments or RMEs that staff are assigned to clean.⁵⁸ The OIG found SPS staff competencies were not up-to-date. System and SPS leaders had not consistently conducted, tracked, or documented competency assessments as required.

Per VHA policy, “[c]ompetencies must be assessed when an employee begins working in SPS, during the orientation period, and throughout employment in SPS.”⁵⁹ Competencies are generally assessed at one- or three-year intervals based on the facility’s annual SPS risk analysis, but may be more frequent based upon changes in existing procedures or manufacturer’s IFUs.⁶⁰

Following the development of an SOP and its associated training, the Chief of SPS is responsible for developing corresponding competency assessments and ensuring that all staff involved in reprocessing duties are trained and proficient prior to performing the sterilization task. The Chief of SPS must maintain and track competency assessments in each employee’s training folder.⁶¹

While on-site, the OIG team observed that SPS staff competencies were stored in binders that were not organized in any discernable manner. The team was unable to determine if the employee’s competencies were current because the tool provided by the facility did not indicate the staff member’s date of hire or if the SOP on the list was current. According to the ADPCS, SPS leaders were working on an electronic tracking system that allowed for better monitoring and notification.

The former Chief of SPS acknowledged falling behind on validating staff’s competency two years before leaving SPS in May 2018. SPS staff attributed the deficiency to the lack of staff, unplanned prolonged staff leave, loss of the RME coordinator, and a reduction in the SPS pay grade.⁶² The OIG obtained emails that supported the former Chief of SPS communicating the

⁵⁷ Deputy Under Secretary for Health for Operations and Management Memorandum, *Competency Assessment for Employees Reprocessing Critical and Semi-critical Reusable Medical Equipment*, April 1, 2017.

⁵⁸ VHA Directive 1116(2). SPS management must verify each SPS employee’s individual competency by at least two of the following three methods: requiring a return demonstration, observing the employee conducting the cleaning process, or witnessing the employee’s verbal understanding of the specific competency.

⁵⁹ VHA Directive 1116(2).

⁶⁰ VHA Directive 1116(2). The annual risk assessment “involves identifying the potential source of a process failure, estimating the likelihood that such a failure will occur, assessing the consequences if that failure does occur, and assessing how prepared the facility is to manage the failure.” For example, an instrument of RME that is not used often but is technically difficult to reprocess may require an annual competency, while one that is easy to clean and used often could be completed every three years.

⁶¹ VHA Directive 1116(2).

⁶² The terms deficiency and vulnerability were both used in NPOSP reports. For the purposes of this report, the OIG will use the term deficiency.

ongoing staffing difficulties and the inability to complete training and competencies to the ADPCS.

A review of the RME Committee meeting minutes confirmed there were several periods of time when SPS staff competency assessments and the risk analysis of SOPs were delinquent due to prolonged staffing issues, the change in RME coordinators, and SPS leaders covering front-line staff duties. Although efforts were underway to complete and update SOPs, implement training, and validate competencies, the OIG found that the maintenance of over 200 SPS competencies is a monumental task while being short staffed with unfilled key positions such as an educator, an RME coordinator, and other leaders in SPS.

Staffing

Success in any department or operations is reliant upon having the proper resources necessary to complete the work, which includes having adequate and capable staff. The significant challenges associated with hiring and maintaining SPS staff are well known to VHA medical facilities across the country, and have been identified as problematic in recent OIG reports.⁶³ An audit conducted by Government Accountability Office in 2017 through 2018 identified the top five SPS operational challenges cited by VISNs and selected VA medical centers officials; three of the five top challenges were related to SPS workforce needs (lengthy hiring timeframes, consistent overtime, limited pay, and professional growth).⁶⁴

The OIG determined that system leaders had significantly underestimated system SPS staffing levels needed to support a facility that provided complex surgical procedures.

In July 2016, NPOSP reviewers recommended system leaders utilize the NPOSP SPS staffing tool to determine staffing needs.⁶⁵ In May 2018, NPOSP reviewers determined that system leaders had not completed the SPS staffing tool and reported, “SPS staffing levels are too low to sustain an effective RME Program.” Corrective actions recommended by NPOSP reviewers included that system leaders re-evaluate SPS staffing coverage needed to meet patient care needs by using the NPOSP SPS staffing tool, prioritize hiring vital SPS positions, and consider using contract agency SPS technicians until full-time positions were secured.

⁶³ VA OIG, *Alleged Concerns in Sterile Processing Services at the New Mexico VA Health Care System, Albuquerque, New Mexico*, Report No. 17-04593-10, October 31, 2018; VA OIG, *Critical Deficiencies at the Washington DC VA Medical Center*, Report No. 17-02644-130, March 7, 2018.

⁶⁴ U.S. Government Accountability Office, GAO-18-474, *Improved Oversight Needed for Reusable Medical Equipment*, August 2018. <https://www.gao.gov/assets/700/693710.pdf>. (The website was accessed on October 1, 2018.)

⁶⁵ The NPOSP provides a staffing algorithm tool designed to help facility SPS departments estimate needed staffing levels based upon workload volumes for decontamination, preparation, sterilization, and RME program development.

VISN and system leaders and staff informed the OIG team that SPS staffing shortages and vacancies had been a long-standing problem to include chronic recruiting challenges and maintaining adequate SPS staff. The ADPCS said that in conjunction with the former Chief of SPS, attempts were made to address SPS staffing challenges, poor retention, and personnel issues prior to the TJC visit in February. The ADPCS stated it was difficult to recruit SPS technicians, as the position had been downgraded on a national level from a general schedule 6 to a 5 position. This downgrade was also reported in the July 2017 RME committee meeting minutes. The VISN Quality Management Officer told the OIG team that SPS was under-resourced and chronically struggled with staffing and recruitment challenges, and stated this was partially attributed to the increased technical skills required for low pay grade SPS positions. Further, multiple system staff told the OIG team that recruitment and retention challenges were related to SPS staff pay grades that were not competitive with surrounding non-VA hospitals.

System staff explained that the SPS retention challenges were further exacerbated by the physical working conditions in the SPS space. Specifically, VISN and system leaders, and staff described the SPS space as small, windowless, and subject to extreme temperature and humidity levels. The steam pipes ran in the crawl space directly beneath the SPS floors, and during the summer months, the temperature would rise to over 90 degrees requiring staff to be rotated in and out of the space every 15 minutes to cool down. The temperature was partially remediated when an additional cooling system was placed in the courtyard and piped into the SPS area.

The impact of the SPS staffing shortages was reflected throughout RME Committee meeting minutes, email exchanges, and interviews with key staff throughout the system. The system RME Committee meeting minutes from June and July 2017 reported that the former Chief of SPS had been unable to complete the NPOSP staffing tool due to competing priorities and program demands (system leaders were unable to provide RME Committee meeting minutes from August 2017 through May 2018). The former Chief of SPS and multiple system staff reported that they had to forego some administrative responsibilities, such as training and SOPs, to keep the department operational and meet the complex surgical demands. The former Chief of SPS reported covering shifts for SPS technicians at the facility and the ACC-N, in addition to working after hours and on weekends. In October 2017, after four additional SPS staff left the Service, an OR manager reported they had assigned OR surgical technicians and OR nurses to rotate through SPS on a daily basis to keep the Service operational. The OR assistance was discontinued in March 2018 following the TJC survey, as the OR manager stated it became too complicated to keep 25 OR staff competencies validated on all RME.

The former Chief of SPS reported keeping the ADPCS informed of SPS vacancies, and SOP and training backlogs. In addition, the former Chief of SPS provided the OIG team with email documentation which appeared to verify the communication. During interviews, these emails and the content of such were also noted by the system Associate Director.

Table 2. SPS Staffing

Employees	April 14, 2015	April 4, 2018	May 22, 2018	January 30, 2019
Full-Time Employee Equivalents (FTEs) ⁶⁶	19	27	43	54*
Vacancies	9	12	Unknown	17*

Source: Provided by a system Human Resource Specialist on December 11, 2018, and by the ADPCS on January 31, 2019

**The numbers reported for January 30, 2019, do not reflect the additional 10 FTEs (9 of which were vacant) allotted for the planned implementation of a third SPS shift.*

Following the initial TJC survey, system leaders recognized the need to increase SPS resources, and in April 2018, they increased staffing from 19 to 27 FTEs. However, 12 of the 27 FTE positions were vacant, leaving the burden of covering two SPS shifts across two campuses (35 miles apart), and all programmatic and administrative responsibilities to 15 FTEs. System leaders have now determined SPS operations requires 54 FTEs (versus 15), and an additional third shift with 10 employees bringing the total to 64 FTEs.

The OIG determined that inadequate SPS staffing levels was the primary contributing factor to the former Chief of SPS and Assistant Chief's inability to maintain administrative and programmatic functions such as the identified deficiencies with SOPs, training, and competencies.

5. Surgical Case Cancellations and Outsourcing

The OIG determined facility surgical cases were canceled and outsourced to a non-VA hospital due to unaddressed issues in SPS that were identified in the May 2018 NPOSP "For Cause" site review.

The OIG team reviewed a facility database, developed by Surgical Services leaders, that was used to track outsourced surgical patients during the timeframe of limited SPS capabilities. Between May 13, 2018, and January 31, 2019, 1,975 surgical patients were outsourced into the community. The OIG noted that 15 of these patients did not have a final disposition documented in the database. The OIG team reviewed the EHRs of these 15 patients to determine the disposition and ensure their care was completed. The OIG team found that two patients declined surgery, and the other 13 patients either had surgery or were scheduled for surgery at a later date.

⁶⁶ FTEs were the total number of full-time employee positions approved for the service, while the vacancies were approved positions that had not yet been filled by a permanent employee.

SPS Reprocessing Limitations

The OIG determined that limitations imposed on SPS staff regarding the number of trays that could be processed; the lack of critical water; and the previously mentioned SOPs, training, and competencies all affected Surgical Services staff's ability to perform complex surgical cases after May 2018.

Besides the infrastructure (particularly the shortage of critical water) and the SPS staffing issues addressed above, in August 2018 system leaders limited the number of surgical trays that could be reprocessed to 15 instrument trays per day. Surgical Services leaders told the OIG they were not consulted on the determination nor did they understand the rationale for limiting the number to 15 trays per day. The OIG was provided conflicting reports on how the decision was made to limit instrument trays to 15 per day.

Surgical instruments are assembled on trays according to surgical specialty and surgeon preference, and then sterilized for surgical cases. Grouping instruments on a tray is limited by guidelines for reprocessing and weight limitations.⁶⁷ There is a large variation regarding how many trays are used for a surgical case; for example, an excision of a skin growth may require one tray of instruments while an orthopedic total joint replacement may require 8 to 10 trays.

Surgical Scheduling Limitations

The system has a high complexity status that serves as a referral center for other VA facilities, including the state of New York; thus, the loss of the facility's surgical capabilities impacted other VA facilities and required additional referrals to non-VA hospitals.⁶⁸

After the May 2018 NPOSP site review, system leaders determined that SPS staff could not meet the demands of surgery, and limited the types and number of surgical cases that could be scheduled and performed at the facility. On May 14, system surgical leaders and staff began to transition all ophthalmology cases to Yale. On May 15, surgical schedule limitations were implemented in total joint surgeries, open heart surgeries, and robotic and advanced laparoscopic

⁶⁷ Association Perioperative Registered Nurses (AORN). AORN Reference Center. *What is the weight limit for instrument sets to be sterilized?* 2012-2019. <https://www.aornguidelines.org/faq/content?gbosid=403629>. (The website was accessed on March 16, 2019.)

⁶⁸ VHA assigns all its inpatient medical centers an operative complexity (standard, intermediate, or complex) and provides guidance regarding infrastructure requirements. VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This directive expired May 31, 2015, and has not been recertified or replaced; Deputy Under Secretary for Health (DUSHOM). *VA Operative Complexity Designation*. September 8, 2016. http://vaww.dushom.va.gov/DUSHOM/surgery/Operative_Complexity.asp. (The website was accessed on November 6, 2018.)

surgeries.⁶⁹ In addition, the number of cystoscopies were reduced from 14 to 9 procedures.⁷⁰ Later that summer, the ability to schedule surgical cases was dependent upon which SOPs were completed. The Associate Chief of Surgery provided clinical oversight and subject matter expertise to support the safe and organized methodology for scheduling surgical cases. The Associate Chief of Surgery met weekly with service coordinators, operating room staff, and anesthesia providers to review scheduled surgical cases.

On November 3 (Saturday), an Environmental Service staff member dislodged a sprinkler head while cleaning the ceiling in the operating room and caused a flood. System leaders were immediately notified of the event. Due to flood remediation, no further surgeries were scheduled or performed until January 28, 2019.

As compared to months of previous calendar years, the volume of cases performed in the operating room had been dramatically affected (see Figure 1).

⁶⁹ “Robotic surgery is a method to perform surgery using very small tools attached to a robotic arm. The surgeon controls the robotic arm with a computer.” National Institute of Health/U.S. National Library of Medicine. Medline Plus. Medical Encyclopedia. <https://medlineplus.gov/ency/article/007339.htm>. (The website was accessed on April 10, 2019.) A laparoscopy is a type of surgery where a thin tube called a laparoscope into a patient’s abdomen or a woman’s reproductive system. The laparoscope is attached to a camera and sends images to a video monitor. This allows the surgeon to view inside the body without major trauma to the patient. <https://medlineplus.gov/lab-tests/laparoscopy/>. (The website was accessed on April 22, 2019.)

⁷⁰ A cystoscopy is a type of surgery where a thin lighted tube with a small camera on the end is inserted through the urethra into the bladder. There are two types of cystoscopes: rigid and flexible. <https://medlineplus.gov/ency/article/003903.htm>. (The website was accessed on April 22, 2019.)

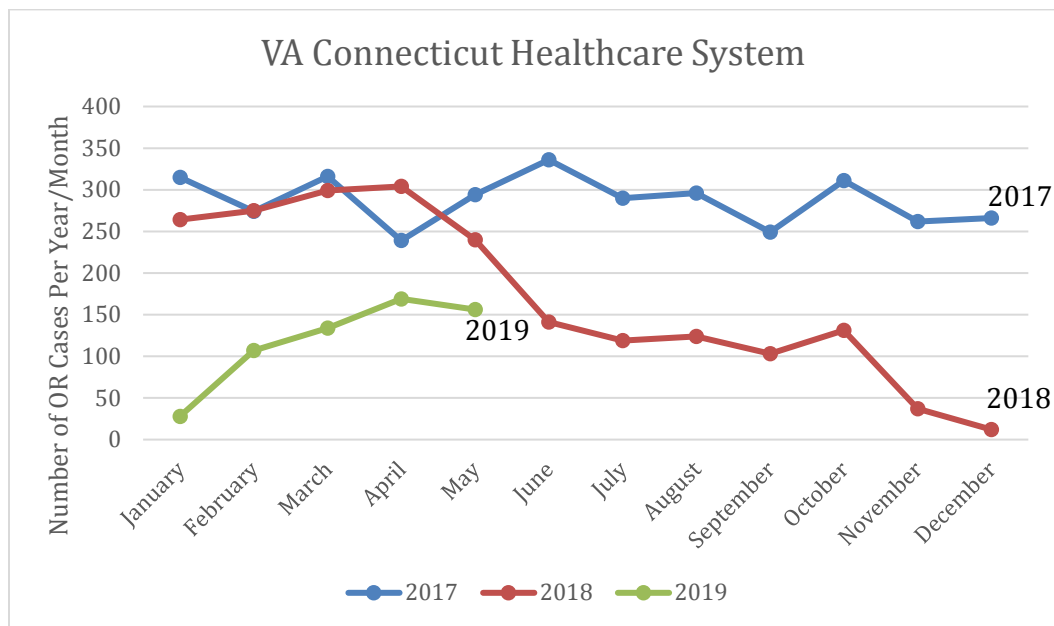


Figure 1. OR cases per month and year
Source: VA OIG analysis of 53T Surgical Services data

Surgical Services Actions to Preserve Continuity and Quality of Care

Tracking Cases

System Surgical Services leaders identified patients who required surgery and offered them Choice or facilitated direct referrals to a non-VA hospital.⁷¹ Due to issues in SPS, Surgical Services leaders developed a process for coordinating and tracking all surgical cases outsourced by the facility.⁷²

The process included the development of a facility database completed by the Associate Chief of Surgical Services, Chief of Neurosurgery (who was also a biostatistician), and Information Technology staff. The system surgical patients were tracked beginning on May 14, 2018. The Associate Chief of Surgery collaborated weekly with the eight specialty Surgical Services

⁷¹ VHA Veterans Choice Provider Agreement. Choice refers to the Veterans Access, Choice, and Accountability Act of 2014 which authorizes the VA to pay for non-VA hospital care for eligible veterans.

⁷² Outsourced cases included those that were scheduled at the VA but could not be completed at the VA and those that were not yet scheduled.

coordinators (service coordinators).⁷³ Service coordinators, including post anesthesia care and intensive care nurses, reviewed patient EHRs to determine if surgeries had been completed or were pending completion at a non-VA hospital. The service coordinators followed up with the patients, facility surgeons, and non-VA hospitals to facilitate care. Surgical cases that were not completed or scheduled were marked as pending in the facility tracking database. The system Administrative Officer for Surgery would identify all pending cases weekly and send them to the section chiefs.

Documentation and Privileging Challenges

In order to preserve the continuity and quality of care for patients, Surgical Services staff worked with Information Technology staff and other community locations to access patient's clinical information.

VA neurosurgeons and orthopedic surgeons with privileges at Yale could perform surgical procedures on VA patients on VA time. However, those who did not have privileges at Yale had to apply for privileges.

August 10–13, 2018, Surgical Cases

Senator Blumenthal specifically requested that the OIG review facility surgical cases that were canceled between August 10 and August 13, 2018, due to contamination of two surgical trays. According to the Chief of Surgery, bioburden was found on a routine ear, nose, and throat instrument tray; therefore, Surgical Services leaders decided to implement an “SPS stand down” on a Friday afternoon for the scheduled Monday surgical cases to ensure there were no major problems with SPS equipment or processes.⁷⁴ The OIG reviewed 10 scheduled surgical cases between August 10–13, and found three cases for otolaryngology (ear, nose and throat), one for general surgery, one for urology, and five for mental health. The OIG excluded the five cases in mental health as they did not require the use of RME. Of the five remaining operating room cases, two cases were performed prior to the stand down without complications, two were canceled by the patients due to illness, and one case was rescheduled.

⁷³ Service coordinators work closely in consultation with surgeons to provide preoperative education to patients, follow up on required medical clearance for surgery, monitor the preoperative work up of the patient and report any abnormalities to surgeon, resident, and primary care physician, and make referrals to community care as required. The role of the service coordinator has expanded as described above to assist in preserving continuity and quality of care to patients.

⁷⁴ Bioburden is the number and type of variable organisms which an item is contaminated.
<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/glossary.html#B>. (The website was accessed April 9, 2019.)

Other Facility Projects Affecting Patient Volume

In addition to the reduction of surgical cases, on July 6, 2018, the cardiac catheterization lab suspended services due to scheduled remodeling. Prearranged plans were made for cardiac catheterization lab patients to receive services at a non-VA hospital. On April 22, 2019, the cardiac catheterization lab reopened. The remodeling of the cardiac catheterization lab has expanded the cardiac diagnostic and interventional services the system can provide. In addition, the completion of the cardiac catheterization lab has allowed the Emergency Department to resume accepting acute cardiac patients.

Other Services Affected by SPS Limitations

The inability to perform surgical procedures at the facility also impacted other specialties. The Chief of the Emergency Department told the OIG that patients had been diverted from the Emergency Department to non-VA hospitals (usually Yale) because acute surgical issues may have required operating room interventions. The Chief of Medicine informed the OIG that the diversion had impacted inpatient workload, and all specialties experienced a decline in admissions. The Cardiac Service had been impacted beyond the expected decrease in census due to the cardiac catheterization lab remodeling.

Nursing care units such as the medical surgical and intensive care units experienced a decrease in census of 50 percent or more. The OIG team was told that nurses were fearful for their jobs or positions due to the decreased census at the system. Staff also reported a lack of transparency; although there were “issues,” there was no explanation.

6. Patient Safety and Undue Burden

Patient Safety Related to SPS Concerns

While on-site, the OIG team asked interviewees if they were aware of any patients who had an adverse event. Interviewees identified a patient whose surgical procedure was canceled after receiving general anesthesia.⁷⁵ The operating room staff had identified a sterile instrument that may have been contaminated, and they were unable to locate a set of back-up instruments to proceed with the surgery.

⁷⁵ General anesthesia is the induction of a loss of unconsciousness by medication administration. In this state, the patient will be unarousable to verbal, touch, and painful stimuli. Usually an endotracheal tube is inserted to maintain airway patency. In addition, a mechanical ventilator may be required to provide ventilation. Freeman BS. Stages and Signs of General Anesthesia. In: Freeman BS, Berger JS. eds. *Anesthesiology Core Review: Part One Basic Exam*, New York, NY: McGraw-Hill; 2014.
<http://accessanesthesiology.mhmedical.com/content.aspx?bookid=974§ionid=61588520>. (The website was accessed on April 18, 2019.)

According to VHA, an “adverse event may result from acts of commission or omission (e.g. administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment).”⁷⁶ According to the American Society for Anesthesiologists, “[a]nesthesia is responsible for management and preservation of patient safety, on-site medical direction of any nonphysician who participates in the delivery of anesthesia care to the patient. The physician anesthesiologist should participate in a planned program for evaluation of quality and appropriateness of the anesthetic care of patients and should participate in resolving identified problems.”⁷⁷ Communication between anesthesia and OR staff may have prevented the patient being anesthetized prior to assurance that the necessary operating room equipment was appropriately sterilized and available for use.

Patient A

The patient, in their 70s, was referred in summer 2018 to the facility’s Neurosurgery Service by a provider at another VA facility within VISN 1.⁷⁸ The patient complained of bilateral hip and leg pain for greater than 10 years and had a history of spinal stenosis⁷⁹ in the lumbar⁸⁰ (low back) region.

One month later, a facility neurosurgeon evaluated the patient for complaints of many years of low back pain which radiated down the back of both legs, associated numbness and weakness with standing or walking, and limited ambulation to 100 feet. The neurosurgeon documented the

⁷⁶ VHA Handbook 1050.01.

⁷⁷ American Society of Anesthesiologists, Standards and Guidelines: *Guidelines for Patient Care in Anesthesia*, <https://www.asahq.org/standards-and-guidelines/guidelines-for-patient-care-in-anesthesiology>. (The website was accessed on May 29, 2019.)

⁷⁸ The OIG uses the singular form of they (their/them) to protect the patient’s privacy.

⁷⁹ Spinal stenosis is a narrowing of the canal (space) within your spine where the spinal cord and nerves travel. Mayo Clinic Patient Care & Health Information: Spinal Stenosis. <https://www.mayoclinic.org/diseases-conditions/spinal-stenosis/diagnosis-treatment/drc-20352966>. (The website was accessed on March 20, 2019.)

⁸⁰ Lumbar refers to the lower portion of the spine Mayo Clinic Patient Care & Health Information: Spinal Stenosis. <https://www.mayoclinic.org/diseases-conditions/spinal-stenosis/diagnosis-treatment/drc-20352966>. (The website was accessed on March 20, 2019.)

patient may benefit from an open L4 laminectomy⁸¹ with L4-5 medial facetectomies.⁸² In addition, the neurosurgeon outlined the risks associated with the proposed surgery.

The neurosurgeon documented “we currently have equipment issues in the facilities’ operating room, and we are behind schedule for surgeries with a waiting list.” The neurosurgeon further explained to the patient and their family that the service may not be able to offer surgery within 30 days; if the facility could not provide the surgery, the patient’s local VA would coordinate care at a non-VA hospital.

Two weeks after the neurosurgery appointment, a facility physician assistant performed a preoperative anesthesia evaluation. The neurosurgeon discussed the planned surgery with the patient and documented a plan of the surgery’s risk and benefits with the patient.

The following day, the patient was admitted to the Neurosurgical Service for spinal surgery under general anesthesia with endotracheal intubation.⁸³ At 8:29 a.m., the patient was brought to the operating room, and at 8:36 a.m., general anesthesia was administered to the patient. The patient was monitored by a certified registered nurse anesthetist.⁸⁴ OR staff voiced concern for potential contamination of the equipment that was to be used in the surgery. The EHR noted that when the OR “staff realized there was not a back-up instrument set available in the event of issues with the original instruments, [the] case was aborted.” The neurosurgeon had not yet made any incisions. Medications were administered to reverse the effects of the general anesthesia. At 9:33 a.m., the patient was extubated and taken to the post anesthesia care unit for recovery.⁸⁵

The neurosurgeon and the system Chief of Surgery discussed the events with the patient’s family, answered questions, and documented a disclosure of the adverse event in the patient’s

⁸¹ A laminectomy is the removal of the back part of a bone in the spine. Mayo Clinic Patient Care & Health Information: Spinal Stenosis. <https://www.mayoclinic.org/diseases-conditions/spinal-stenosis/diagnosis-treatment/drc-20352966>. (The website was accessed on March 20, 2019.)

⁸² A medical facetectomy is removal of the medial (middle-close to center) facet joints. Each vertebral body in the spine have tiny joints called facet joints. Kang K, Rodriguez-Olaverri JC, Schwab F, Hashem J, Razi A, Farcy JP. Partial facetectomy for lumbar foraminal stenosis. *Adv Orthop*. 2014. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4119622/pdf/AORTH2014-534658.pdf>. (The website was accessed on April 5, 2019.)

⁸³ National Institute of Health/U.S. National Library of Medicine. MedlinePlus (Medical Encyclopedia), *Endotracheal Intubation*. <https://medlineplus.gov/ency/article/003449.htm>. (The website was accessed on April 4, 2019.) Endotracheal intubation is a medical procedure in which a tube is placed into the windpipe (trachea) through the mouth or nose and is used to keep the airway open to provide oxygen, medicine, or anesthesia.

⁸⁴ A certified registered nurse anesthetist is an advanced practice registered nurse with graduate level education who provides anesthesia to patients for surgery or procedures. American Association of Nurse Anesthetist. *Become a CRNA*. <https://www.aana.com/membership/become-a-crna>. (The website was accessed on March 24, 2019.)

⁸⁵ Extubated describes the removal of an endotracheal tube. Tobin MJ, Laghi F. Chapter 59. Extubation. In: Tobin MJ, eds. *Principles and Practice of Mechanical Ventilation*, 3e New York, NY: McGraw-Hill; 2013. <https://accessanesthesiology.mhmedical.com/content.aspx?bookid=520§ionid=41692306>. (The website was accessed on April 4, 2019.)

EHR. Later that day, the patient was discharged home in good condition. The patient was referred to Yale for the neurosurgical procedure.

Nine days later, the patient had a laminectomy at Yale and was discharged home after two days. The patient received their follow-up care at the VA referring facility and at Yale.

Additional Risk

General anesthesia can result in serious complications, such as heart attacks, strokes, respiratory difficulties, allergic reactions, or even death. Patients may experience a variety of uncomfortable minor side effects, such as nausea and vomiting, difficulty passing urine, sore throat due to the breathing tube, and confusion

The patient required additional general anesthesia when the surgical procedure was performed at a later date. While the patient did not suffer complications related to general anesthesia, the patient was placed at additional risk.

Undue Burden

For purposes of this report, the OIG interpreted “undue burden” to mean an inconvenience for patients requiring an alternative location for the provision of health care that may cause frustration, confusion, or disturbances.

During interviews, staff described the undue burden on patients:

- Patients were unable to receive care at the system, per their preference.
- Patients had surgery at a non-VA hospital, although their primary care physician and mental health providers were still at the VA.
- Coordination of patient medications and any required durable medical equipment was complicated when patients were discharged from a non-VA hospital.
- Patients had to pay for parking at Yale.

The OIG was unable to quantify the inconveniences that led to frustration, confusion, or disturbances in the patient’s VA healthcare experience.

7. Surgical and Post-operative Infection Rates

Surgical Site Infections in Neurosurgery, Orthopedic Surgery, and Vascular Surgery

According to the facility’s Hospital Epidemiology/Infection Prevention Program and Plan, the Infection Prevention and Control Program, “surveils surgical site infections on a six-month rotating schedule targeting high risk and high volume procedures,” and surveils all positive

cultures.⁸⁶ Components of the system's Infection Control and Epidemiology program included the collection and analysis of data relevant to hospital epidemiology, cluster/outbreak investigations, and consultation on infection risk assessment/problem solving for all departments.⁸⁷ Collaboration exists between the system Surgical Services and the Infection Prevention and Control Program Committee.⁸⁸

The OIG determined system leaders and staff instituted actions to address surgical site infections that had been identified in three surgical specialties (neurosurgery, orthopedic surgery, and vascular surgery) between 2017 and 2018. The system's Infection Prevention and Control Program provided oversight and review for a multidisciplinary evaluation of the surgical site infections in those surgical specialty areas. The OIG medical consultant reviewed system leaders' analysis of surgical site infections in the neurosurgery, orthopedic surgery, and vascular surgery, and determined the system leader reviews were comprehensive and thorough.

As the facility staff had not resumed performing these complex cases, the OIG could not evaluate the efficacy of the actions taken.

2018 Surgical Site Infection

After reviewing the facility's analysis of its surgical site infections in neurosurgery, orthopedic surgery, and vascular surgery, the OIG requested a list of all surgical site infections between October 1, 2016, and September 30, 2018, and focused its review on 23 patients who underwent surgery and developed an infection in 2018. The OIG determined that while there were concerns that SPS issues may have led to surgical site infections, there were other contributory factors

⁸⁶ Surveillance is close and continuous observation or testing. <https://www.merriam-webster.com/dictionary/surveillance>. (The website was accessed on April 8, 2019.) VA Connecticut Healthcare System Hospital Epidemiology/Infection Prevention Program and Plan. October 2018.

⁸⁷ VHA Directive 1113(2), *Management of Infectious Disease and Infection Prevention and Control Programs*, November 7, 2017. A multidisciplinary Infection Prevention and Control Program Committee is generally chaired by the Hospital Epidemiologist and must include representation from infectious disease, infection prevention and control, pharmacy, environmental management services, facilities management, surgery, SPS, pathology and laboratory medicine, employee health, safety/industrial hygiene, community living center, providers, nursing (Associate Chief, or equivalent), and facility leaders. VA Connecticut Healthcare System Hospital Epidemiology/Infection Prevention Program and Plan. October 2018. An epidemiologist is a professional who studies a branch of medical science that deals with the incidence, distribution, and control of disease in a population. <https://www.merriam-webster.com/dictionary/epidemiologist>. (The website was accessed on April 9, 2019.); The Association for Professionals in Infection Control and Epidemiology "is the leading professional association for infection preventionists." Their mission is to "create a safer world through the prevention of infection." <https://apic.org/About-APIC/About-APIC-Overview>. (The website was accessed on March 20, 2019.)

⁸⁸ VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013. "VA Surgery Quality Improvement (VASQIP) serves as the primary tool for measurement of the quality of surgical outcomes. ASQIP data are collected from VHA facilities for designated types of surgical procedures based upon probability of adverse events based on probability of postoperative adverse events in accordance with standardized data definitions. The clinical data is validated, formatted, and analyzed to characterize prevailing mortality and morbidity rates, both unadjusted and risk-adjusted."

such as infections at the time of surgery, open wounds, and ischemic bowel.⁸⁹ In addition, the patients were considered at higher risk for surgical site infections as evidenced by their American Society of Anesthesiologists (ASA) scores of 3 and 4.⁹⁰ As the OR was closed during our inspection, SPS reprocessing was limited; and therefore, the OIG team was unable to fully evaluate the impact of deficient SPS processes on the system's rate of surgical site infections.

8. Other Concern: Residency Program

Under 38 U.S.C. § 7302(a)(1), the VA “shall develop and carry out a program of education and training of health personnel” for its own needs and those of the nation.⁹¹ As one of its four statutory missions, the VA conducts education and training programs for health professions trainees to enhance the quality of care provided for patients. In accordance with this mission, education and training efforts are conducted through coordinated programs in partnership with affiliated U.S. academic institutions. VA conducts the largest education and training effort for health professionals in the United States.⁹²

The OIG team was told that the system residency program had been affected by the limitations imposed on Surgical Services due to SPS issues, and the flood in the operating room that resulted in a shutdown of Surgical Services from November 3, 2018, through January 28, 2019.

The system has residency programs in medicine, psychiatry, and surgical services with an annual resident FTE of 186 in over 35 specialties. The majority of the residency programs are affiliated with Yale, while a smaller number is affiliated with the University of Connecticut. Twenty-four percent of the system's residents are assigned to surgery.

The OIG interviewed surgeons and reviewed Surgical Services Committee meeting minutes that identified concerns that the residency programs were in jeopardy and residents not having the opportunity to care for patients:

- Low patient volume for several specialties in medicine and surgery
- Limited educational experience

⁸⁹ Ischemic refers to a deficient supply of blood to a body part. <https://www.merriam-webster.com/dictionary/ischemic>. (The website was accessed on April 8, 2019.)

⁹⁰ The ASA developed a physical status classification system to categorize a patient's physiological status to assist in predicting operative risk (ASA 1—A normal healthy patients, ASA 2—A patient with mild systemic disease, ASA 3—A patient with a severe systemic disease that is not life-threatening, ASA 4— A patient with a severe systemic disease that is a constant threat to life, ASA 5—A patient who is not expected to survive without the operation.) Doyle DJ, Garmon EH. American Society of Anesthesiologists Classification (ASA Class) [Updated 2019 Jan 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK441940/>. (The website was accessed on April 10, 2019.)

⁹¹ 38 U.S.C. § 7302(a)(1). <https://www.law.cornell.edu/uscode/text>. (The website was accessed on April 2, 2019.)

⁹² U.S. Department of Veterans Affairs. Office of Academic Affiliations. https://www.va.gov/oaa/oaa_mission.asp. (The website was accessed on February 2, 2019.)

- Limited opportunities for comprehensive surgical experience (clinic, hospital, follow-up)

Conclusion

The OIG reviewed various concerns at the facility. The OIG found that system leaders and the building infrastructure contributed to inefficiencies and delays in SPS remediation efforts.

During interviews with staff from various disciplines, over 50 percent of the interviewees informed the OIG team that they felt system leaders, specifically the Director and the ADPCS, had handled the SPS remediation efforts poorly. Staff consistently identified two primary themes: (1) the lack of inclusiveness and shared decision-making with system staff who had a working knowledge of and/or expertise in Surgical Services, OR, and SPS; and (2) the lack of effective communication.

Facility Management Services did not have consistent leadership, and projects were routinely delayed or postponed due to frequent infrastructure emergencies. Concerns expressed by staff regarding the inability to maintain environmental controls in an older facility were valid. VISN and system leaders told the OIG team that facility infrastructure problems with HVAC and plumbing included the building that houses the inpatient medical and surgical units and SPS.

While the OIG validated an increase in surgical cancellations and surgical cases outsourced to non-VA hospitals, Surgical Services leaders took a proactive approach to preserve the continuity and quality of care provided to their patients.

The OIG reviewed the care of a patient who experienced an adverse event directly related to the SPS limitations. While the patient did not suffer complications, they were placed at additional risk.

Facility staff described the inconveniences patients had expressed, the most frequent of which was the preference to receive care at the VA hospital versus a non-VA hospital. Additional concerns included the coordination of discharge medications and durable medical equipment from the VA hospital after having procedure in a non-VA hospital, and parking fees when having procedures at Yale.

Surgical site infections were identified in neurosurgery, orthopedic surgery, and vascular surgery between 2017 and 2018. The OIG determined the analyses performed by the Infection Prevention and Control Program were comprehensive, and although no definite source or process was identified in the review, system leaders instituted actions to decrease the rate of infections. Twenty-three patients were reported as having a surgical site infection in FY 2018; however, the OIG determined there were other factors such as infections at the time of surgery, open wounds, ischemic bowel, and other severe systemic diseases that could have contributed to the surgical site infections.

The system residency program had been affected by the limitations imposed on surgery due to SPS issues and the flood related 12-week operating shutdown. The OIG team concurred with concerns that the residents expressed to facility staff such as low patient volumes for several specialties in medicine and surgery, limited educational experiences and opportunities for comprehensive surgical experience (clinic, hospital, follow-up), and documentation challenges due to different patient EHR computer systems at the system and Yale.

The OIG made 11 recommendations.

Recommendations 1–11

1. The Veterans Integrated Service Network 1 Director provides oversight for the timely implementation of Office of Inspector General recommendations directed to the VA Connecticut Healthcare System Director.
2. The Veterans Integrated Service Network 1 Director ensures the timely completion of hiring actions at the VA Connecticut Healthcare System until staffing deficiencies in Sterile Processing Services and Facility Management Services are fully resolved.
3. The VA Connecticut Healthcare System Director ensures clinical leaders with working knowledge of and/or expertise in operating room, surgery, and Sterile Processing Services are included in the decision-making and resolution of Sterile Processing Service remediation efforts.
4. The VA Connecticut Healthcare System Director ensures the development and implementation of a clear action plan to establish communication, foster collaboration, and restore system staff trust in system leaders, and, as necessary, consult with Veterans Health Administration's National Center for Organizational Development.
5. The VA Connecticut Healthcare System Director provides oversight for the timely completion of the projects impacting Sterile Processing Services and Surgical Services that remain pending.
6. The VA Connecticut Healthcare System Director ensures that the development, review, and revision of standard operating procedures is completed, and that a sustainable process is in place to maintain standard operating procedures.
7. The VA Connecticut Healthcare System Director ensures that all Sterile Processing Services staff complete and maintain Sterile Processing Services training and competencies.
8. The VA Connecticut Healthcare System Director ensures that Sterile Processing Services leaders maintain a staffing plan that includes an accurate number of authorized positions that is based on clinical and administrative workload and other appropriate measures, and includes contingencies for staffing areas with high attrition rates.
9. The VA Connecticut Healthcare System Director ensures that surgery and anesthesia staff evaluate the readiness of all supplies and equipment for use before anesthetizing a patient.

10. The VA Connecticut Healthcare System Director evaluates and reports the impact on and identified needs of the VA Connecticut Healthcare System residency program.

11. The VA Connecticut Healthcare System Director works collaboratively with Veterans Integrated Service Network 1 Director to ensure the timely implementation of future Sterile Processing Services planned projects.

Appendix A: Sequence of Events

**Table A.1. Summary of Relevant Events
from February 13, 2018, through February 1, 2019**

Date	Event
February 13–16, 2018	TJC full unannounced survey; system received a Preliminary Denial of Accreditation
May 8–11	NPOSP conducted a “For Cause” site review
May 11	Emergency department placed on diversion due to SPS reprocessing issues
May 15	Surgical eye cases sent to Yale
May 17	[Associate Chief of Surgery initiated weekly meetings] with case coordinators [to plan upcoming surgical cases] All services told to book at least one case less than the number of their trays [Cystoscopy surgical case] reduced [from 14] to 9 cases/session
June 6	Chief of Surgery participated in weekly VISN call
June 7	[Unable to perform] sequential [robotic surgical] or advanced [laparoscopic] cases; only two [total] joints/week (not same type on same day)
June 10	[Discontinued robotic surgical case], advanced laparoscopy (no laparoscopy instruments except disposables)
June 11	[Total] Joints placed on hold
June 12	First meeting [held for] SPS workgroup [SPS Action Group]
June 18	Surgical leaders spoke to OR staff concerning SPS issues
June 20	[System] Director spoke with OR staff concerning SPS issues Chief of SPS from [another facility] within VISN 1 detailed as SPS acting chief
July 6	VISN [Chief Medical Officer] met with Surgical Leaders to strategize solutions
July 17	Chief of Medicine and Chief of Surgery met with Associate Director to request acceleration and coordination of [SPS] repairs Associate Director to discuss with Director
July 18	Director set up Executive Integrated Project Team [First Meeting held July 20, chaired by Hospital Epidemiologist and Associate Director]
August 10	[Identified] two ENT [ear, nose and throat] trays with SPS issues [first surgical instrument tray had bioburden, second tray had blue enzymatic stains on liner]; all cases stopped in OR and diversion until COB 8/13/18
August 17	[TJC] gave accreditation with follow-up site visit (Official notice 9/6/18)
August 21	Limited to 15 surgical instrument trays/day processed in SPS (includes scopes)
August 29	First OR nurse trained to help SPS

Alleged Deficiencies in Sterile Processing Services and
Decreased Surgical Volume at the VA Connecticut HCS

Date	Event
September 2	Heat/humidity issue [found] in Building 1; room with instruments in it with no data on whether parameters met standards [All instruments processed before 9/4/ to be reprocessed per SPS workgroup [SPS Action Group]]
September 6	Met with Yale Nursing/SPS to discuss VA options; Yale [did not have] have capacity to process VA instruments
September 7	[Discontinued vascular surgical] implant cases; still no [laparoscopic] instruments (except disposables)
September 27	[Acting Chief of SPS's detail ended]
October 2	Water spotting [found] on instruments (maybe from steam shut-downs); neurosurgery case canceled, and no laminectomies until further discussion
October 16–17	[NPOSP visit] - recommended facility discontinue all ortho, vascular, neurosurgery (any complex cases) until [critical] water project finished
October 22	Lack of staffing in SPS resulted in suspension of OR services for any cases beyond the seven trays being processed; emergency department on diversion from 8am to 8pm
November 2	Executive in Charge and National group [visited]; green light [given] to get cases back to system and re-establish complex surgical procedures, [wanted] plan in one month
November 3	Entire OR flooded by [broken sprinkler head; contents of OR rooms removed for professional cleaning]
November 3	OR closed/emergency department on diversion due to flood
November 12	SPS/RME/IP Director reports to VA Connecticut HCS
December 10–13	OIG was here to investigate SPS issues
December 31	New leak [found] between [OR] Rooms 6 and 7; room 7 still with ceiling leak
January 3	TJC [returned and found facility] compliant with its action plans
January 8	[OR] Construction completed and released to EMS [Environment Management Services] for terminal cleaning
January 10	OR space turned over to Head Nurse Manager for move-in SPS began reprocessing trays to be put back in the OR
January 14	Set up OR simulation in OR room 1
January 15	[Set up] PACU [post anesthesia care unit] simulation
January 28	First elective cases done
January 30	Removed ER [emergency room] diversion; Installation of the [critical water system]] completed
February 1	Executive in Charge's Chief of Staff, VISN, System Leaders [met] with OIG

Source: Timeline provided by system surgical leaders; modified for brevity by the OIG team.

Appendix B: System Deficiencies

**Table B.1. May 2018 NPOSP-Identified System Deficiencies
Requiring Immediate Action**

Location/Department	Deficiency	OIG Review of System Resolutions
SPS	Biological Indicator ⁹³ “early release.”	SOP was developed for appropriate incubation of processed biological indicators and release of sterilized RME. ⁹⁴
Eye Clinic Staff (Facility and ACC-N)	Clinic staff reprocessing semi-critical RME in eye clinics.	Transferred RME reprocessing responsibilities from the Eye Clinic to SPS. SOP was developed in accordance with manufacturer’s IFU. Staff training and validation of staff competence was initiated.
SPS	Enzymatic solution is utilized during the cleaning process (at the manual cleaning sink and ultrasonic cleaner) of intraocular instrumentation in SPS at the facility.	Refer to VHA Memorandum; <i>Reprocessing of Intraocular Instrumentation: The Use of Enzymatic Solution</i> . February 22, 2017. SOP was updated. Staff training and validation of staff competence was initiated. “Stop the Line.” ⁹⁵ Ophthalmology Surgeries were transferred in May to Yale New Haven Health System (Yale).
SPS	Workflow in SPS decontamination does not flow continuously from dirty to clean, including transportation of case carts containing soiled RME in close proximity to stored clean case carts.	Workflow revised in SPS. SOP for transportation of RME. ⁹⁶
Endoscopy	Storage cabinet for high-level disinfected endoscopes located in an area that did not meet	Bronchoscopes reprocessed, and storage location changed to an SPS area that met environmental conditions.

⁹³ VHA Directive 1116(2). A biological indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

⁹⁴ VA Connecticut Health Care System. #2440-001, *Action for Positive Biological Test*, July 18, 2018.

⁹⁵ Stop the Line refers to a measured response from VHA staff members when detecting errors or identifying areas of concern in the health care delivery process. VHA Office of Quality, Safety, and Value. *Stop the Line*. March 12, 2018. <http://vaww.oqsv.med.va.gov/stoptheline/>. (The website was accessed March 6, 2019.)

⁹⁶ VA Connecticut Healthcare System. #8000-003, *Transporting Reusable Medical Equipment*, June 6, 2018.

Location/Department	Deficiency	OIG Review of System Resolutions
	minimal environmental conditions (temperature and humidity monitoring and air flow).	
Endoscopy	High-level disinfectant endoscopes at risk for cross contamination due to door open to a common hallway.	Unable to determine sustainability because there was no documented action.
OR	The reprocessing (cleaning and high-level disinfectant) of semi-critical RME (transrectal ultrasound probes and transvaginal probe), was performed in an area located in the OR. The decontamination area is adjacent to an OR suite where patient procedures are performed.	"Stop the Line" for reprocessing in the OR. ⁹⁷ Reprocessing of semi-critical RME transferred to the SPS department.

Source: May 8, 2018, NPOSP For Cause site review

⁹⁷ "Stop the Line" refers to a measured response from VHA staff members when detecting errors or identifying areas of concern in the health care delivery process. VHA Office of Quality, Safety, and Value. *Stop the Line*. March 12, 2018. <http://vaww.oqsv.med.va.gov/stopheline/>. (The website was accessed March 6, 2019.)

Appendix C: February 2019 Facility Visit

At the invitation of the Executive in Charge, Office of the Under Secretary for Health, the OIG team participated in a second visit to the facility in February 2019 and found that system leaders continued to struggle to keep the SPS and ORs functional.

The OIG team met with VISN and system leaders and the Chief of Staff for the Under Secretary of VHA to discuss the status of the system's SPS and facility operating room issues. System leaders provided a review of the issues, stating that it had been a daily challenge to keep operations running due to infrastructure issues and problems obtaining de-ionized water for SPS. In addition, several floods and leaks in the operating room created a problem with the continuity of operation standards.

System leaders stated that the OR was operating at full capacity, although clinical staff were not performing neurosurgeries, orthopedic surgeries, or vascular surgeries. The OIG team was told that a major OR renovation was scheduled for the summer of 2019, which would require three trailers; however, they were having difficulty locating space to place the OR trailers on the facility grounds.

System leaders also stated that a short-term plan was focused on obtaining an SPS trailer (three to four months away). Once the trailer is obtained, a facility leader stated that they "need to pull electricity and water from the street, which is an issue."

The OIG team found that system leaders had not filled the staffing vacancies originally reported during the OIG's first site visit, and SPS leaders had not initiated a third shift which would enable 24-hour, 7-day coverage.

Appendix D: Future Plans

Mobile Sterile Processing Unit

In the fall of 2018, system leaders explored the prospect of a mobile sterile processing unit. The OIG team was informed that the chosen mobile trailer required a connection to the facility building. During a January 2019 interview, system leaders reported that the contract had been awarded, and the proposal was escalated to the VISN Director. In February, a system leader informed the OIG team that initial negotiations indicated a 24-month turnaround timeframe; however, with assistance from VHA Central Office, the time frame was decreased to 15 months.

Operating Room HVAC Project

The operating room HVAC system had been described by operating room staff as an ongoing issue because temperatures had exceeded parameters. VHA updated requirements regarding HVAC parameters in September 2017.

System leaders reported that a large project was planned for the fall of 2019 to replace the facility's OR HVAC system that would shut down the facility operating rooms. System leaders planned to lease three trailers to continue surgical services; however, no major surgeries would be performed during this time. According to Surgical Services leaders and a Facility Management Service engineer, the design had been completed, and was being contracted for construction. The project would include the modification of the neurology department, creation of an opening from the facility to the mobile operating rooms, and the maintenance of a self-contained HVAC and air pressure system located in an operating room on the third floor. Construction was estimated at four months; however, the entire process could take up to one year.

New SPS

The OIG team was told that an \$17 million project was approved for the system to build a new SPS department. A Facility Management Service engineer stated that system leaders wanted to start the project as soon as possible, and that the scope of the project was submitted in June 2018. System leaders were trying to get the project awarded to an architectural engineering firm in March or April 2019. It was reported that it would take approximately 450 days for a design and capacity study to be completed. Construction was expected to take one and a half to two years, with the completion estimated between three to five years.

Appendix E: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: September 5, 2019

From: Director, VA New England Healthcare System (VISN 1)

Subj: Healthcare Inspection—Deficiencies in Sterile Processing Services and Decreased Surgical Volume at the VA Connecticut Healthcare System, Newington and West Haven, Connecticut

To: Director, Office of Healthcare Inspections, (54HL06)

Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. Thank you for the opportunity to review the draft report of the Healthcare Inspection-Deficiencies in Sterile Processing Services and Decreased Surgical Volume at the VA Connecticut Healthcare System, Newington and West Haven, Connecticut. I appreciate the Office of Inspector General's oversight and the extensive work done as part of this review. We acknowledge there are improvements to be made and we are committed to timely implementation of Office of Inspector General recommendations.
2. I have reviewed the Healthcare System Director's action plan and projected completion dates. I concur with the plan and have complete confidence that the plan will be effective. In the Facility Director's response to the draft report, the facility has provided some much needed context to the report, which provides a more balanced view of the level of effort that the facility undertook to remedy SPS deficiencies over the past two years. It is important to note that the facility prioritized harm reduction as the guiding principle for responding to these challenges. Thus, while we can and do acknowledge room for improvement in the facility response, we must also acknowledge the spirit of patient safety which was an important part of the leadership team's decision-making process for these past two years. VISN 1 will assist the Healthcare System's leadership in reaching full implementation in a timely manner.

(Original signed by:)

Ryan Lilly, MPA

Director, VA New England Healthcare System (VISN 1)

Comments to OIG's Report

Recommendation 1

The Veterans Integrated Service Network 1 Director provides oversight for the timely implementation of Office of Inspector General recommendations directed to the VA Connecticut Healthcare System Director.

Concur.

Target date for completion: February 1, 2020

Director Comments

The VA Connecticut Healthcare System leadership will generate monthly written action plans documenting progress on all Office of Inspector General recommendations. These action plans will be submitted to the VISN 1 Director for review, with further analysis by the VISN Quality Management Officer, to ensure timely implementation of the recommendations. The threshold for completion will be 90% compliance for three consecutive months.

Recommendation 2

The Veterans Integrated Service Network 1 Director ensures the timely completion of hiring actions at the VA Connecticut Healthcare System until staffing deficiencies in Sterile Processing Services and Facility Management Services are fully resolved.

Concur.

Target date for completion: February 1, 2020

Director Comments

The Veterans Integrated Service Network 1 Director established recurring meetings with VA Connecticut Healthcare System leadership to review the status of the Sterile Processing Service remediation efforts. These calls include data on Sterile Processing Services staffing vacancies, recruitment, and progress toward planned staffing levels. Facilities Management Chief and Assistant Chief were hired and on board in June 2019.

A projected staffing model was created and completed based upon clinical and administrative needs as well as anticipated needs to staff two mobile trailers and a third shift to enhance services to end users. A contract to provide SPS Technicians was established as a contingency plan to staff areas with high attrition rates and keep the service fully staffed. According to this model SPS is fully staffed at this time. The VISN 1 Director established recurring meetings with VA Connecticut Healthcare System leadership to review the status of the SPS remediation efforts. These calls include data on Sterile Processing Services staffing vacancies, recruitment

and progress toward planned staffing levels. Facilities Management Services Chief and Assistant Chief were hired and on board in June 2019.

Appendix F: Director Comments

Department of Veterans Affairs Memorandum

Date: October 10, 2019

From: Acting Director, VA Connecticut Healthcare System (689)

Subj: Healthcare Inspection—Deficiencies in Sterile Processing Services and Decreased Surgical Volume at the VA Connecticut Healthcare System, Newington and West Haven, Connecticut

To: Director, VA New England Healthcare System (VISN 1)

1. We appreciate the opportunity to review the Office of Inspector General (OIG) report and provide comments. We concur with the concerns and recommendations of the OIG and deeply regret the impact that deficiencies in our sterile processing had on our Veterans and our healthcare system. As part of our commitment to be a high reliability organization we took The Joint Commission (TJC) and the National Program Office for Sterile Processing (NPOSP) reports very seriously. We developed and implemented plans to address identified concerns. We respectfully submit the following additional factual information on our effort to ensure Veteran safety during the period of remediation. We have organized our comments by broad themes discussed in the OIG report.

2. National Program Office for Sterile Processing (NPOSP) Assist Site Review (October 16-18, 2019)

- a. VA Connecticut Healthcare System invited the NPOSP to conduct an assist site review in October 2018. The goal was to have the NPOSP provide input on our progress since the May 2018 NPOSP site visit. Additionally, this was an opportunity to review prioritization of interventions and adjust recommendations by the NPOSP. The October 2018 NPOSP report acknowledges the progress VA Connecticut made since the May 2018 inspection. The reviewers noted “a tremendous improvement from the previously identified multiple non-conformities from the May 2018 NPOSP visit.”

3. Staffing Shortages

The OIG report correctly identifies issues with staffing in Sterile Processing Service (SPS). These issues were also identified by the NPOSP May 2018 For Cause Site Review. After the NPOSP site review in May 2018 the following actions were taken to address staffing:

- a. Seventeen VA CT Healthcare System staff were detailed for various periods of time to support remediation of RME (Reusable Medical Equipment) deficiencies noted in the NPOSP May 2018 report. Six staff from other VA facilities were detailed to assist for varying periods of time. This included an SPS Chief from another VA within VISN1 for close to 4 months.
- b. VA CT leadership advertised detail opportunities in SPS throughout our national network.
- c. A contract for more SPS personnel was put into place.
- d. A new organizational chart and structure for SPS/RME was developed. We added an SPS Technician, supervisor, and lead technician at both campuses; an Assistant Chief at Newington; an RME Educator; a second RME Coordinator; a Non-Critical RME

Coordinator, an RME/SPS QM Nurse; an OR/SPS Liaison Nurse, and a Nurse 4 SPS/RME/IP Director. As of August 30, 2019, 76% of the new positions have been filled (this includes the new non-critical RME staff).

4. Lack of Subject Matter Experts (SME) on the SPS Action Group

We agree that there were significant opportunities for improvement in the membership and functioning of the SPS Action Group. We took the following actions to increase the expertise of this group:

- a. The Bedford VA SPS Chief was detailed to VA CT from June 4, 2018 to September 30, 2018 as part of the Action Team in the role of Acting SPS Chief.
- b. The Action group also had weekly calls with the NPOSP, consulted with the VISN Quality Management Officer, the VISN 1 Patient Safety Officer, and three additional consultants who were asked to review our SPS processes. The ADPCS, Chief Hospital Education, Hospital Epidemiologist all completed the NPSOP Level 1 training modules in June 2018. The NPOSP Director and Educator came to VA CT July 10-12, 2018 and presented a 3-day modified level 2 training for all SPS staff, OR staff, RME Coordinator, Infection Prevention and QM staff, ADPCS, Chief Hospital Education, and detailed staff.

5. Lack of Transparency and Communication

We agree that there were opportunities for improvement in communication and want to clarify that the following additional efforts were made to enhance communication:

- a. In May 2018 huddles were established with Surgery/OR and Action Team.
- b. Between June 2018 and August 2018, the SPS Action Group frequently met with the OR/Surgery. At the end of August 2018, a scheduled one-hour weekly meeting was formalized with Surgery/OR and the Action Team. This meeting continued through November 2018 and reconvened in late December 2018. In January 2019 the new SPS/RME Nurse Director took over from the Action Team representing SPS.
- c. EIPT (Executive Integrated Project Team) was formed at the end of July 2018. The EIPT met weekly until March 2019. The Chiefs of Surgery, Medicine, and Anesthesia as well as the OR Nurse Manager were among the members of the EIPT. In December 2018, the Director invited OR/Surgery staff to join the weekly EIPT meetings.
- d. The Chief Quality Manager Chief, or a representative, attended the Nurse Manager Performance Improvement meetings to provide TJC/SPS updates.
- e. Updates on progress with addressing items from the May 2018 NPOSP report were reviewed at each RME Committee meeting.
- f. Updates were presented monthly at the Infection Prevention Committee through June 2019.
- g. As part of the MSEC (Medical Staff Executive Committee) Infection Prevention (IP) quarterly report, the Hospital Epidemiologist reported on progress related to remediation of issues identified in the May 2018 NPOSP report.

6. Shortage of Critical Water

- a. An acceptable critical water (deionized water [DI]) system had been installed at the time of the February OIG visit when the OR had just re-opened after the November 3, 2018

flood. That system has since been replaced with a newer system that will remain in place until our new SPS facility is completed. The system is hooked up to all sinks and equipment that provide final rinse for instruments/equipment.

7. Missing Ceiling Tiles

- a. It should be noted that the ceiling was in the process of being changed from a drop ceiling to a continuous hard ceiling. The West Haven campus SPS Sterrad Room ceiling was replaced 9/6/19-9/9/19.

8. Lack of Automated Cart Washer

- a. This project required extensive demolition and construction within the SPS space to accomplish. It has been a year-long project that is close to completion as of October 10, 2019.

9. Standard Operating Procedures (SOPs)

- a. We want to clarify that any instruments/equipment that did not have current SOPs were not used or reprocessed until a current SOP was in place.
- b. As of September 19, 2019, there are at least 260 SPS SOPs (increased from the 200 SOPs noted in the OIG report).
- c. On August 8, 2019 stakeholders (including the OR Nurse Manager, Director SPS/RME/IP, RME Coordinator, SPS Assistant Chief, SPS/OR Liaison, OR Educator, and Hospital Epidemiologist) met to review our processes for developing SOPs and identified opportunities for improvement.

10. Surgical Case Cancellations and Outsourcing

- a. We agree that deficiencies in SPS had a significant impact on the ability of VA Connecticut Healthcare System to provide care to surgical patients.
- b. Many of the patients who were cared for at a non-VA hospital were seen at our academic affiliate. In most cases, these patients were cared for by VA physicians on VA time at the affiliate.

11. Infrastructure

- a. Additional measures have been taken to address the temperature and humidity issues within SPS. Underfloor insulation (to temper heat/humidity coming from the steam conduits that run below SPS) was added in SPS since the OIG inspection. It was rare this past summer that the temperature/humidity rose to levels experienced in prior years.
- b. It should be noted that it is common for SPS departments to be located in the basement/sub ground levels of facilities thus they do not have windows.

12. Appendix timeline

- a. On June 4, 2018 the Bedford VA SPS Chief was detailed to VACT.
- b. On June 20, 2018 the Chief of Surgery, the OR Nurse Manager, and the Hospital Epidemiologist met with the OR staff along with the Director.

- c. On August 16, 2018 an EIPT conference call was added to the EIPT weekly in person meeting that included the OR Nurse Manager, the Chief of Surgery, and the Chief of Medicine.
 - d. The August 21, 2018 limitation of 15 surgical instrument trays/day being processed in SPS did not include scopes.
- 13.** We are grateful to all of our employees who are deeply committed to ensuring the safety our Veterans. Through their dedication we have been able to implement significant improvements in sterile processing. We appreciate the recommendations of the OIG and have provided an action plan to address the findings. We look forward to continuing to improve sterile processing, transparency, inclusivity, and communication at the VA Connecticut Healthcare System.
- 14.** If you have any questions, please contact the Director at 203-937-3825.

Respectfully,

(Original signed by:)

Lisa S. Lehmann, MD, PhD
Acting Director, VA Connecticut Healthcare System
Chief Medical Officer, VA New England Healthcare System (VISN 1)

Comments to OIG's Report

Recommendation 3

The VA Connecticut Healthcare System Director ensures clinical leaders with working knowledge of and/or expertise in operating room, surgery, and Sterile Processing Services are included in the decision-making and resolution of Sterile Processing Service remediation efforts.

Concur.

Target date for completion: February 1, 2020

Director Comments

In January 2019, leaders of SPS, the operating room (OR), and Surgery at VA Connecticut Healthcare System began meeting with the leadership of the prior SPS work group, including the Associate Director of Patient Care Services, to review and prioritize the completion of SOP's for OR instruments and to provide an update on the progress of related projects. This meeting will be transitioned to a new meeting structure within the existing framework of the OR Management Committee. The OR Management Committee will meet monthly with the VA Connecticut Chief of Staff, Associate Director of Patient Care Services, Assistant Director, and leaders from SPS/OR, Facilities Management Service, and other stakeholders to discuss issues related to the progress and planning of the SPS/OR remediation efforts.

Minutes and action items from the OR Management Committee meetings will be routinely shared with all participants in the multidisciplinary OR Management Committee, including OR, SPS, and Surgery leadership. The minutes and action items will also be shared with all clinical leadership through Medical Staff Executive Committee. The progress of the remediation will be shared with the SPS, OR, and Surgical staff through the OR Management Committee Minutes. The threshold for completion will be 90% compliance for three consecutive months.

Recommendation 4

The VA Connecticut Healthcare System Director ensures the development and implementation of a clear action plan to establish communication, foster collaboration, and restore system staff trust in system leaders, and, as necessary, consult with VHA's National Center for Organizational Development.

Concur.

Target date for completion: February 1, 2020

Director Comments

VA Connecticut Healthcare System is working collaboratively with an outside consulting group and VA New England Healthcare System Organizational Development staff as part of a culture acceleration initiative aimed at improving overall communication and restoring trust. Based on employee input, a team is working to determine the best methods and venues to promote better communication and transparency throughout our organization. The Healthcare System has implemented a weekly senior management all-employee electronic newsletter, increased senior level visibility throughout the facility via regularly scheduled rounds, hosted all employee town hall meetings, is offering employees the opportunity to meet informally in small groups with the acting director, and created twice monthly leadership meeting that include all supervisors to foster transparency, improve communication, and restore trust. The threshold for completion will be 90% compliance with leadership meetings for three consecutive months.

Recommendation 5

The VA Connecticut Healthcare System Director provides oversight for the timely completion of the projects impacting Sterile Processing Services and Surgical Services that remain pending.

Concur.

Target date for completion: February 1, 2020

Director Comments

On February 20, 2019 an interdisciplinary team was formalized to provide oversight for the timely completion of the projects impacting SPS that remain pending. This team is comprised of facility leadership, Facilities Management Service, SPS, and Infection Prevention. Surgical Service Leadership has been added to this team. Projects overseen include: critical water availability, ceiling corrections, installation of automatic cart washer, and trailer retrofit. Progress and updates are provided monthly to facility senior leadership, VISN 1 leadership, the National Program Office Sterile Processing, and VHA's Office of Capital Asset Management Engineering and Support. The threshold for completion will be 90% compliance with monthly update submissions to leadership.

Recommendation 6

The VA Connecticut Healthcare System Director ensures that the development, review, and revision of standard operating procedures is completed, and that a sustainable process is in place to maintain standard operating procedures.

Concur.

Target date for completion: February 1, 2020

Director Comments

The SPS/RME Director, SPS Assistant Chief, OR Nurse Manager, OR Educator, OR/SPS Nurse Liaison, and Hospital Epidemiologist have outlined the standard operating procedure (SOP) development, review, and revision process used to develop new SOPs and review existing SOPs as scheduled. Review of existing SOPs occurs on a rolling basis and recurs on an annual, every 2-year or every 3-year cycle depending on the risk assessment for the individual SOP. We continue to use an Excel spreadsheet to track SPS SOPs that includes the next review date. The spreadsheet can be sorted by review date as a quick way to see what is coming near date for review. On a monthly basis the SPS Administrative Officer (AO) will flag to the SPS Chief/Asst Chief which SOPs are coming close to their end dates and in need of review. For further enhancement the VA Quality Consultative Division (QCD) is in the process of being implemented in SPS at VA Connecticut. SOP status update will be provided through the RME Committee at least monthly. The threshold for completion will be 90% compliance with the AO flagging SOPs in need of review and SOP status updates to the RME Committee for three consecutive months.

Recommendation 7

The VA Connecticut Healthcare System Director ensures that all Sterile Processing Services staff complete and maintain Sterile Processing Services training and competencies.

Concur.

Target date for completion: February 1, 2020

Director Comments

All SPS staff new hires are assigned SPS Level 1 Talent Management System training modules upon hire. SPS leadership facilitates and ensures all modules are completed within 90 days of hire via the Talent Management System supervisor tracking mechanism (implemented in January of 2019). All required competencies will continue to be monitored by SPS leadership for timely completion via the competency tracker. Continuation of monthly SPS education/training and in services tracking will occur via an electronic spreadsheet. SPS leadership will collaborate with a new RN SPS Educator, with the Quality Consultative Division (QCD), and an SPS Education Management System folder will be created for tracking. The threshold for completion will be 90% maintenance of training and competency folders for three consecutive months.

Recommendation 8

The VA Connecticut Healthcare System Director ensures that Sterile Processing Services leaders maintain a staffing plan that includes an accurate number of authorized positions that is based on clinical and administrative workload and other appropriate measures, and includes contingencies for staffing areas with high attrition rates.

Concur.

Target date for completion: September 6, 2019

Director Comments

A projected staffing model was created and completed based upon clinical and administrative needs as well as anticipated needs to staff two mobile trailers and a third shift to enhance services to end users. A contract to provide SPS Technicians was established as a contingency plan to staff areas with high attrition rates and keep the service fully staffed. According to this model SPS is fully staffed at this time.

OIG Comments

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

Recommendation 9

The VA Connecticut Healthcare System Director ensures that surgery and anesthesia staff evaluate the readiness of all supplies and equipment for use before anesthetizing a patient.

Concur.

Target date for completion: February 1, 2020

Director Comments

A system of recurring checks of equipment has been established. When a case is booked, the surgical case coordinators enter a request containing the case type and any special equipment or instruments needed. Two days before the surgery, the requests are reviewed by the OR staff to ensure all equipment, supplies, and instruments are available in the OR or SPS, including loaner instruments. One day before surgery, all needed supplies and instruments are placed on the case carts, except for loaner instruments which stay in SPS until the morning of surgery. On the day of the surgery the instruments, including loaners, are opened in the room and the instruments are inspected and validated as ready for use by the OR staff before the patient enters the room. A time out will occur prior to anesthetizing the patient and will include verification that all supplies, equipment, and instruments, including loaners, necessary for the surgical procedure are

present, available, and ready for use. As a final check, a “surgical pause” will then be conducted immediately prior to incision. Staff will randomly audit at least 5 high frequency procedures/month, which include a time out. The threshold for completion will be 90% compliance with surgeries proceeding with appropriate equipment, supplies, and instruments in a monthly random audit for three consecutive months.

Recommendation 10

The VA Connecticut Healthcare System Director evaluates and reports the impact on and identified needs of the VA Connecticut Healthcare System residency program.

Concur.

Target date for completion: September 10, 2019

Director Comments

The system Director has evaluated the impact on and identified needs of the VACT residency program. A report of the impact has been submitted to the VISN CMO and VISN Director for validation.

VA Connecticut Healthcare System surgical capabilities have been reestablished to allow the inpatient units to function at normal capacity and our inpatient census is back to its usual level. The diversity and volume of patients admitted to our inpatient wards has restored our teaching environment to an excellent level. Almost all 24 surgical specialty residents assigned to the VA Connecticut Healthcare System are currently operating at the VA. Orthopedic joint replacements and Neurosurgical spine cases are not being done at VACT. These residents are operating at Yale on many VA patients. It is anticipated that all surgical residents will be fully back in the VA by the end Quarter 1 of FY20.

OIG Comments

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

Recommendation 11

The VA Connecticut Healthcare System Director works collaboratively with Veterans Integrated Service Network 1 Director to ensure the timely implementation of future Sterile Processing Services planned projects.

Concur.

Target date for completion: February 1, 2020

Director Comments

On October 12, 2018 a recurring monthly meeting was formalized to work collaboratively with VISN 1 Director to, among other objectives, ensure the timely implementation of future SPS planned projects. This meeting is comprised of facility leadership and VISN 1 leadership. Future projects overseen include: a commercial mobile sterile processing unit, operating room HVAC project, and a new minor SPS project. The threshold for completion will be submission of minutes of the meetings to the VISN Director for three consecutive months.

OIG Contact and Staff Acknowledgments

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