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VETERANS HEALTH ADMINISTRATION

Continued Sterile Processing Services Deficiencies and Facility Leaders' Failures at the Carl Vinson VA Medical Center in Dublin, Georgia

Healthcare Inspection | **24-02277-69** | **March 6, 2025**

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Executive Summary

In spring 2024, while conducting a routine healthcare inspection at the Carl Vinson VA Medical Center (facility) in Dublin, Georgia, the VA Office of Inspector General (OIG) learned of an incident in which a "rectal tray" that had been reprocessed by Sterile Processing Services (SPS) included surgical instruments that were pitted, stained, and tarnished, and used during a patient procedure.[1] Due to a series of SPS-related deficiencies and risk to patient safety found in previous OIG reports, the OIG opened a healthcare inspection to determine how surgical instruments that were not suitable for service (nonconforming instruments) were used during a patient procedure.[2] The OIG inspection identified further SPS-related deficiencies, a continuation of previously identified deficiencies, and a failure of facility leaders to address those deficiencies.

Reusable Medical Devices and SPS

Reusable medical devices (RMDs) are instruments or devices that healthcare providers can reprocess and reuse on another patient.[3] "Reprocessing is a term used to describe the steps involved in making an RMD safe for patient care, including decontamination and [high-level disinfection], or decontamination and sterilization."[4] In Veterans Health Administration (VHA) facilities, SPS staff have a primary responsibility to ensure that patients receiving medical care "are provided with appropriate reprocessed RMD."[5] Failure to properly clean, disinfect, or

[1] A rectal tray is a set of surgical instruments for use in a variety of procedures involving the rectum. The facility's rectal tray contains 90 surgical instruments. If one of the tray's instruments is contaminated, the whole tray is considered contaminated.

[2] VA OIG, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 20-00130-06, November 12, 2020; all recommendations have been closed; VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 22-01315-90, March 6, 2024; As of September 2024, one Veterans Integrated Service Network recommendation and four facility recommendations remain open; For the purposes of this report, the OIG uses the term *nonconforming* to describe reusable medical devices in disrepair or with compromised surfaces such as cracking, discoloration, or staining.

[3] "What are Reusable Medical Devices?" Food and Drug Administration, accessed September 25, 2024, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/what-are-reusable-medical-devices.

[4] VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. During the inspection, VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023, was in effect. This policy was amended to VHA Directive 1116(1) on June 13, 2024, and then amended to VHA Directive 1116(2) on September 9, 2024. The amended directives contain the same or similar language related to SPS definitions, responsibilities, and reprocessing requirements. For the purposes of this report, VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023, will be used unless otherwise specified.

[5] VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023.

sterilize RMDs carries significant risk for person-to-person transmission of infectious diseases.[6] The Joint Commission cites instruments in disrepair or with compromised surfaces "may not be able to be effectively sterilized."[7] Additionally, the Association for the Advancement of Medical Instrumentation requires that nonconforming instruments be "identified and controlled to prevent unintended use."[8]

Summary of the Incident

In spring 2024, a surgeon used surgical instruments from a rectal tray while performing a biopsy (procedure) on a patient.[9] After the procedure, an SPS staff member, who was reprocessing the rectal tray, recognized that several instruments had pitting, staining, and tarnishing and alerted the chief of SPS to the nonconforming instruments.[10] The chief of SPS removed the tray from service, notified the Associate Director Patient Care Services (ADPCS), and entered a patient safety report.[11] The ADPCS notified the Veterans Integrated Service Network (VISN) Chief Sterile Processing Officer.

During a routine follow-up appointment approximately two weeks after the procedure, the surgeon documented no postoperative concerns with the patient. According to the acting Facility Director, the risk manager, with input from infection control staff, reviewed the patient's care

[6] Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008, updated May 2019, accessed May 1, 2024, https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html.

[7] The Joint Commission, *Quick Safety*, "Ensuring critical instruments and devices are appropriate for reuse," Issue 62, February 2022, accessed May 30, 2024, https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-64/.

[8] ANSI/AAMI ST90:2017, *Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities*, 8.3, October 26, 2017. "The health care organization shall verify that processes and product that do not conform to requirements are identified and controlled to prevent unintended use or delivery."

[9] *Cleveland Clinic*, "Biopsy," accessed September 12, 2024, https://my.clevelandclinic.org/health/diagnostics/15458-biopsy-overview. A biopsy is a procedure to remove cells, tissue, or fluid to diagnose medical conditions using laboratory tests and techniques. Healthcare providers do biopsies when they identify areas of concern or there are symptoms or signs of certain conditions.

[10] Pitting is a localized type of corrosion with shallow to deep defects that appear as black holes (pits) on an instrument's surface. "Pitfalls to Avoid in Instrument Reprocessing," Outpatient Surgery Magazine, A Division of Association of periOperative Registered Nurses (AORN), accessed September 30. 2024, https://www.aorn.org/outpatient-surgery/article/2007-August-pitfalls-to-avoid-in-instrument-reprocessing.

[11] The Joint Patient Safety Reporting system is a web-based system used by VHA employees to report patient safety events. VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024.

then discussed the results with the previous acting Chief of Staff and determined no disclosure was needed.[12]

Inspection Results

The OIG determined that SPS and operating room staff failed to remove nonconforming surgical instruments from the rectal tray. Moreover, the OIG found additional surgical instruments in nonconforming condition and that, contrary to policy, staff reprocessed and used nonconforming instruments at the facility.

The OIG inspected the rectal tray and observed the nonconformities on several instruments.[13] The OIG also inspected five randomly selected surgical trays from the operating room sterile storage area and found additional nonconforming instruments. SPS staff told the OIG that reprocessing nonconforming instruments was permitted by the chief of SPS and the previous chief of SPS. The chief of SPS shared several reasons that contributed to this practice including, SPS and operating room staff disputing who was responsible for replacing surgical instruments, operating room staff preferring to receive complete trays, and SPS and operating room staff complacency. When asked how nonconforming instruments could have been used during a procedure, the ADPCS responded that it was not from a lack of training or a process issue but a "people issue," explaining that SPS and operating room staff had responsibilities in recognizing nonconforming surgical instruments. The ADPCS shared that challenges exist at the facility in holding employees accountable.

After discovering that nonconforming surgical instruments were used during a patient procedure, SPS staff were retrained on the recognition, identification, and management of surgical instruments in poor condition. However, the operating room nurse manager, who documented a need for a "more rigid inspection of surgical equipment," did not provide similar retraining to operating room staff. The operating room nurse manager told the OIG that "there was no discussion related to training" until facility leaders became involved in June 2024. When the OIG asked why training did not occur prior to June 2024, the operating room nurse manager provided contradictory statements. The OIG expected that after identification of the need for further inspection of RMDs, the operating room nurse manager would have ensured the operating room staff receive training.

The OIG also found facility leaders failed to establish a preventative maintenance program for the sharpening, repair, or replacement of surgical instruments; which along with permitting the practice of reusing nonconforming surgical instruments, increased the likelihood that patients

[12] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. A "disclosure of adverse events refers to the forthright and empathetic discussion of clinically significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future."

[13] The OIG inspectors observed the discoloration without the use of magnification.

were exposed to unnecessary safety risks. The OIG found no evidence of a preventative maintenance program for servicing surgical instruments prior to May 30, 2024, inconsistent with VHA policy established in March 2016.[14] The chief of quality and patient safety and the acting ADPCS attributed the lack of a preventative maintenance program prior to May 2024 to "leadership turnover in both [SPS] and Nursing Leadership."

Failure to Resolve Previous OIG-Identified Deficiencies

The OIG reviewed facility leaders' actions in response to SPS deficiencies identified in the March 2024 OIG report. Facility leaders failed to fully implement CensiTrac, an electronic surgical instrument tracking system, address concerns of the CensiTrac coordinator's performance on implementation, and resolve concerns related to the intended use of an SPS conference and training room.

VHA uses CensiTrac to manage and track RMDs from the beginning of reprocessing, through transporting, storing, and use. Incomplete implementation of CensiTrac prevents the tracking of individual instruments and reprocessing history, which is a risk to patient safety. The OIG found incomplete CensiTrac documentation related to the rectal tray's reprocessing, and additionally found surgical instruments that were not marked or were inappropriately engraved. The Association for the Advancement of Medical Instrumentation standards state that, "healthcare organizations shall identify" individual instruments through direct marking, bar coding, or color coding.[15] Marking individual instruments allows users the ability to track the instruments to specific patient cases.[16]

The OIG also learned that the CensiTrac coordinator, the employee responsible for overseeing the system and instrument marking, faced performance challenges. Facility and SPS leaders were aware of the coordinator's performance deficiencies and the impact on CensiTrac implementation but failed to address those concerns. The chief of SPS reported a lack of support from facility leaders regarding addressing performance concerns. The ADPCS acknowledged responsibility for the leadership failure and noted a lack of handoff between the prior chief of SPS and chief of SPS. As of September 2024, the March 2024 OIG report recommendation

[14] VHA Directive 1116; VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016, rescinded July 17, 2023. The previous version of the SPS directive placed the responsibility for ensuring a preventative maintenance program upon the facility director, ADPCS, and chief of SPS.

[15] ANSI/AAMI ST90:2017*, Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities*, 7.5.3.1, October 26, 2017.

[16] "What are the current surgical instrument labeling techniques?" Censis, accessed July 25, 2024, https://censis.com/blog/what-are-the-current-surgical-instrument-labeling-techniques/.

remained open, and the OIG will continue to review recommendation closure requests from the Facility Director to ensure completion.[17]

After reviewing documentation, the OIG also found that facility leaders did not have a permanent resolution for the March 2024 OIG report recommendation related to the SPS conference and training room used for lunch or breaks, which presented "a risk for contamination and breach of environmental integrity in SPS."[18] As of September 2024, this recommendation was still open, and the OIG will continue to monitor until completed.

The OIG found that frequent changes in leadership positions, along with leadership failures as identified above, likely contributed to the continued SPS deficiencies discussed in this report.[19]

The OIG made three recommendations to the VISN Director related to reviewing patients potentially affected by nonconforming instruments, evaluating whether administrative action is warranted for employees regarding SPS deficiencies at the facility, and performing oversight of the facility's implementation of facility-level action plans and sustainability of identified outcomes.

The OIG made two recommendations to the Facility Director related to ensuring staff's compliance with identification and disposition of nonconforming surgical instruments and training operating room staff to recognize nonconforming surgical instruments.

VA Comments

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

JULIE KROVIAK, M.D.
Principal Deputy Assistant Inspector General,
in the role of Acting Assistant Inspector General,
for Healthcare Inspections

[17] The OIG considers the CensiTrac Instrument Tracking System fully implemented when SPS staff routinely scan each surgical instrument through the full reprocessing cycle. For this to occur, each surgical instrument must be appropriately marked. VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 22-01315-90, March 6, 2024.

[18] VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*.

[19] From January 2022 through September 2023, the SPS chief position turned over four times, which includes the current chief of SPS who started employment at the facility in September 2023. At the time of the inspection, all members of the facility executive leadership team were serving in a temporary capacity.

Contents

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
AORN	Association of periOperative Registered Nurses
ADPCS	Associate Director, Patient Care Services
CSPO	chief sterile processing officer
OIG	Office of Inspector General
OSP	Office of Sterile Processing
RMD	reusable medical device
SPS	Sterile Processing Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to determine how surgical instruments not suitable for service (nonconforming instruments) were permitted for use during a patient procedure at the Carl Vinson VA Medical Center (facility) in Dublin, Georgia.[1]

Background

Reusable Medical Devices

Reusable medical devices (RMDs) are instruments or devices that healthcare providers can reprocess and reuse on other patients.[2] "Reprocessing is a term used to describe the steps involved in making a contaminated item safe for patient care, including decontamination and [high-level disinfection], or decontamination and sterilization."[3] The Centers for Disease Control and Prevention emphasizes that high-level disinfection or sterilization of RMDs is essential in preventing the transmission of infectious pathogens to patients. Conversely, failure to properly clean, disinfect, or sterilize RMDs carries significant risk for person-to-person transmission of infectious diseases.[4]

The Joint Commission cites instruments in disrepair or with compromised surfaces "may not be able to be effectively sterilized."[5] Additionally, the Association for the Advancement of Medical

[1] For the purposes of this report, the OIG uses the term *nonconforming* to describe reusable RMDs in disrepair or with compromised surfaces, such as cracking, discoloration, or staining.

[2] "What are Reusable Medical Devices?" Food and Drug Administration, accessed September 25, 2024, https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/what-are-reusable-medical-devices.

[3] VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. During the inspection, VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023, was in effect. This policy was amended to VHA Directive 1116(1) on June 13, 2024, and then amended to VHA Directive 1116(2) on September 9, 2024. The amended directives contain the same or similar language related to SPS definitions, responsibilities, and reprocessing requirements. For the purposes of this report, VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023, will be used unless otherwise specified.

[4] Centers for Disease Control and Prevention, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008, updated May 2019, accessed May 1, 2024, https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html.

[5] The Joint Commission, *Quick Safety*, "Ensuring critical instruments and devices are appropriate for reuse," Issue 62, February 2022, accessed May 30, 2024, https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-64/.

Instrumentation (AAMI) requires that nonconforming instruments be "identified and controlled to prevent unintended use."[6]

***Figure 1**: Example of nonconformities on surgical instruments including corrosion, pitting, rusting, and stress cracking.*
Source: ANSI/AAMI ST108:2023, Water for the processing of medical devices, August 18, 2023.

Sterile Processing Services

VHA policy states that, "sterile processing capability must be available on-site and sterile instrument sets and Reusable Medical Equipment must be available for all scheduled invasive procedures."[7] In VHA facilities, Sterile Processing Services (SPS) staff have a primary responsibility to ensure that patients receiving medical care "are provided with appropriate reprocessed RMD."[8] VHA uses CensiTrac, an electronic system, to manage and track RMDs from the beginning of reprocessing, through transporting, storing, and use.

[6] ANSI/AAMI ST90:2017, *Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities*, 8.3, October 26, 2017. "The health care organization shall verify that processes and product that do not conform to requirements are identified and controlled to prevent unintended use or delivery."

[7] VHA Directive 1220(1), *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019, amended February 11, 2020.

[8] VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023. The term *reusable medical equipment* was used in previous OIG reports; however, for consistency with VHA policy, the OIG uses the term reusable medical devices (RMDs).

The VHA Office of Sterile Processing (OSP) provides oversight for SPS and RMD operations, based on guidance from the American National Standards Institute (ANSI), AAMI, and the Association of periOperative Registered Nurses (AORN).[9]

The Veterans Integrated Service Network (VISN) chief sterile processing officer (CSPO) serves as the subject matter expert forSPS and collaborates with facility leaders "in achieving the highest quality RMD outcomes," which includes quality assurance analysis to identify and mitigate risks.[10] At the facility level, the Associate Director Patient Care Services (ADPCS) is responsible for oversight and leadership for SPS operations, and the chief of SPS manages the service.[11]

Facility Information

The facility, part of VA Southeast Network (VISN 7), served 42,517 patients from October 1, 2022, through September 30, 2023. The facility has seven outpatient clinics throughout its catchment area of 49 counties in Georgia.[12] Classified by VHA as complexity level 3, the facility provides outpatient and specialty care services, mental health and long-term care services, and acute medical and surgical services.[13]

Prior OIG Reports

A November 2020 OIG report identified multiple facility SPS deficiencies. As of October 2021, the OIG closed eight recommendations regarding SPS administrative processes, quality

[9] "Office of Sterile Processing (OSP)," VHA Office of Patient Care Services, accessed July 29, 2024, https://www.patientcare.va.gov/Office_Sterile_Processing/index.asp; VHA Directive 1116; "About ANSI," ANSI, accessed August 6, 2024, https://www.ansi.org/about/introduction. "The American National Standards Institute (ANSI) is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system," and "is not itself a standards developing organization. Rather, the Institute provides a framework for fair standards development"; "About AAMI," AAMI, accessed July 16, 2024, https://www.aami.org/about-aami/about-aami. The Association for the Advancement of Medical Instrumentation (AAMI) "is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals"; "About AORN," AORN, accessed July 16, 2024, https://www.aorn.org/about-aorn. The Association of periOperative Registered Nurses (AORN) provides evidence-based resources establishing the standards of excellence for every phase of perioperative nursing care.

[10] VHA Directive 1116.

[11] VHA Directive 1116.

[12] The facility has six community-based outpatient clinics located in Albany, Brunswick, Macon, Milledgeville, Perry, and Tifton, Georgia.

[13] The facility is a level 3 facility. VHA Office of Productivity, Efficiency and Staffing, "VHA Facility Complexity Model," October 1, 2023. The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2, and 3. Level 1a facilities are considered the most complex and level 3 facilities are the least complex.

assurance monitoring, reprocessing and storage area physical inspections, and staff competencies.[14]

On March 6, 2024, the OIG published a report containing nine recommendations related to VISN and facility leaders' failure to remediate SPS deficiencies. Two of the recommendations were directed to the VISN 7 Director, and seven were directed to the Facility Director. As of September 2024, one VISN recommendation and four facility recommendations remained open.[15]

OIG Concerns

Given the facility's previous SPS-related deficiencies and open recommendations, the OIG had planned to conduct a follow-up inspection in 2024. However, one month after publishing the March 2024 report, an OIG team conducting a routine healthcare inspection at the facility learned that a "rectal tray," which had been reprocessed by SPS, contained surgical instruments "with staining, physical etching, and possible pitting" and was used during a patient procedure in spring 2024.[16] Due to continued SPS deficiencies and risk to patient safety, the OIG prioritized and opened a healthcare inspection on May 14, 2024, to evaluate the factors that contributed to the use of nonconforming instruments during the spring 2024 patient procedure and conduct a selected review of prior SPS deficiencies.[17]

Scope and Methodology

The OIG initiated the inspection in May 2024, and conducted a site visit on June 11, 2024. The OIG interviewed the acting Facility Director, ADPCS, chief of quality and patient safety, an infection control nurse, an operating room leader and staff; SPS staff, including the chief of SPS and assistant chief of SPS; CensiTrac coordinator; RMD coordinator; and medical supply technician trainer. The OIG also interviewed the VISN CSPO, as well as representatives of the OSP.

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

[15] VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 22-01315-90, March 6, 2024.

[16] A rectal tray is a set of surgical instruments for use in a variety of procedures involving the rectum. The facility's rectal tray contains 90 surgical instruments. If one of the tray's instruments is contaminated, the whole tray is considered contaminated.

[17] VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 22-01315-90, March 6, 2024; VA OIG, *Comprehensive Healthcare Inspection of the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 20-00130-06, November 12, 2020.

The OIG reviewed relevant VHA and facility policies and procedures related to sterile processing and RMD, in addition to AAMI standards and AORN guidelines.[18] The OIG also reviewed committee charters and minutes, contracts, VISN and OSP site visit reports, personnel documentation, manufacturer's instructions for instruments' use, and training records.

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

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

[18] "AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals." "About AAMI," accessed July 16, 2024, https://www.aami.org/about-aami/about-aami; "AORN defines, supports, and advocates for patient and staff safety through exemplary practice in all phases of perioperative nursing care using evidence-based guidelines, continuing education and clinical practice resources." "About AORN," accessed July 16, 2024, https://www.aorn.org/about-aorn.

Summary of Events

In spring 2024, a surgeon used surgical instruments from a rectal tray during a patient's biopsy (procedure).[19] After the procedure, the rectal tray was sent to SPS for reprocessing. While assembling the rectal tray, an SPS staff member recognized that several instruments had pitting, staining, and tarnishing.[20] The SPS staff member showed the nonconforming instruments to the chief of SPS. The chief of SPS, also concerned about the condition of the instruments, removed the tray from service, notified the ADPCS, and entered a patient safety report.[21] The ADPCS then notified the VISN CSPO.

One day later, the chief of SPS provided training to SPS staff on the recognition, identification, and management of surgical instruments in poor condition. The nonconforming rectal tray instruments were used as an example for educational purposes and a poster was placed in the SPS preparation area, reminding staff to not reprocess nonconforming instruments.

Approximately two weeks after the procedure, the surgeon documented no postoperative concerns during a routine follow-up appointment with the patient. After reviewing electronic health records, and from interviews with the surgeon and operating room staff, the OIG was unable to determine which specific instruments from the rectal tray were used during the procedure due to insufficient evidence.

According to the acting Facility Director, the risk manager, with input from infection control nurse, reviewed the patient's care, then discussed the results with the previous acting Chief of Staff and determined no disclosure was needed.[22] The OIG reviewed the patient's electronic health record and found no adverse effects or further surveillance or testing.

[19] *Cleveland Clinic*, "Biopsy," accessed September 12, 2024, https://my.clevelandclinic.org/health/diagnostics/15458-biopsy-overview. "A biopsy is a procedure to remove cells, tissue or fluid to diagnose medical conditions using laboratory tests and techniques. Healthcare providers do biopsies when they identify areas of concern or there are symptoms or signs of certain conditions."

[20] Pitting is a localized type of corrosion with shallow to deep defects that appear as black holes (pits) on the instrument's surface. "Pitfalls to Avoid in Instrument Reprocessing," Outpatient Surgery Magazine, A Division of AORN, accessed September 30. 2024, https://www.aorn.org/outpatient-surgery/article/2007-August-pitfalls-to-avoid-in-instrument-reprocessing.

[21] The Joint Patient Safety Reporting system is a web-based system used by VHA employees to report patient safety events. VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024.

[22] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. A "disclosure of adverse events refers to the forthright and empathetic discussion of clinically significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future."

Inspection Results

1. SPS Deficiencies

The OIG found SPS and operating room staff failed to remove nonconforming surgical instruments from service. The OIG also found an operating room nurse manager did not provide refresher training related to operating room staff's identification of nonconforming surgical instruments, and facility leaders failed to establish a preventative maintenance program prior to May 2024.

Staff Failed to Remove Surgical Instruments from Service

The OIG determined that SPS and operating room staff failed to remove nonconforming surgical instruments from the rectal tray. Additionally, the OIG found that, contrary to policy, staff reprocessed and used nonconforming instruments at the facility, and that additional surgical instruments were in nonconforming condition.

Facility policies require SPS staff to remove RMDs from service if nonconformities are found.[23] Further, end users such as operating room staff are required to remove nonconforming instruments from service and the instruments are not to be used for patient care.[24] Specifically, SPS staff are responsible for inspecting RMDs in the preparation and sterilization phases, and operating room staff are responsible for completing a pre-procedure RMD quality check.[25] VHA policy states that "proper care and management of RMD within VA medical facilities is the responsibility of all employees."[26]

The OIG learned through review of documentation and during interviews that nonconforming surgical instruments from the rectal tray were used during the patient's procedure in spring 2024. While on-site, the OIG observed pitting, discoloration, and engravings on several of the instruments in the rectal tray.[27]

[23] Facility standard operating procedure VHA-V07-557-SPS-SOP-RMD-0002C, "End User Responsibilities for Reusable Medical Devices (RMD)," September 11, 2023; Facility standard operating procedure VHA-V07-557-SPS-SOP-GEN-0001, "Stainless Steel Surgical Grade Instruments," February 15, 2022.

[24] Facility standard operating procedure VHA-V07-557-SPS-SOP-RMD-0002C.

[25] Facility standard operating procedure VHA-V07-557-SPS-SOP-RMD-0002C; Facility standard operating procedure VHA-V07-557-SPS-SOP-GEN-0001.

[26] VHA Directive 1116.

[27] The OIG inspectors observed the discoloration without the use of magnification.

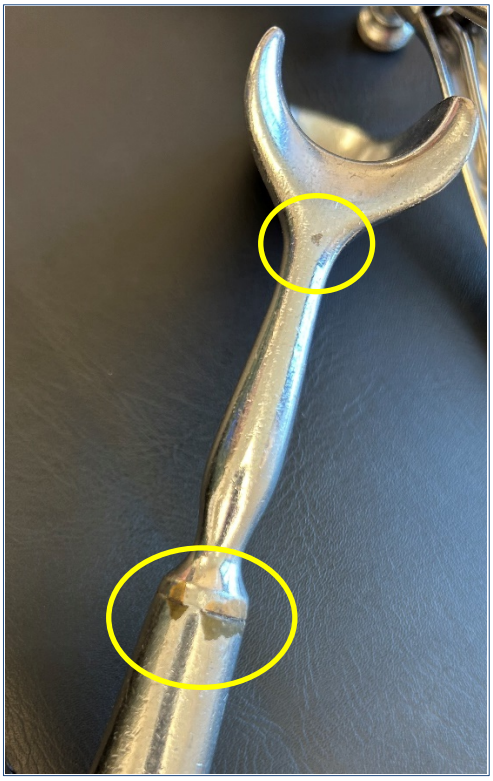

Figure 2. *Nonconforming rectal retractor from the rectal tray.*
Source: VA OIG, June 11, 2024.
Note: Photo taken by OIG staff during the site visit (after being reprocessed and taken out of service and deemed "beyond repair" by a preventative maintenance contract vendor). Yellow circles added by OIG staff indicate areas of nonconformity.

During interviews, SPS staff members involved in reprocessing the rectal tray prior to the procedure, and operating room staff involved in the procedure, reported no concerns with the condition of the instruments. One operating room surgical technician recalled the rectal tray being incomplete but did not recall concerns with the condition of the instruments.

While on-site, the OIG inspected five randomly selected surgical trays from the operating room sterile storage area and found nonconforming surgical instruments and other tray deficiencies. Of the five surgical trays, the OIG found two trays contained instruments with obvious discoloration and one of the sterile rigid containers was missing a screw cover.[28]

The OIG learned from SPS staff that reprocessing nonconforming instruments was permitted by the chief of SPS and the previous chief of SPS. The chief of SPS explained that operating room staff preferred to receive reprocessed surgical trays with all instruments, despite the recognition that some of the instruments were in a nonconforming condition, as well as an ongoing dispute

[28] The OIG inspectors observed the discoloration without the use of magnification.

as to which department—SPS or operating room—had responsibility for replacing surgical instruments. The chief of SPS described a culture of staff complacency in SPS and the operating room. The chief of SPS also attributed SPS deficiencies to an overall lack of nursing oversight. When asked how nonconforming instruments could have been used during a procedure, the ADPCS responded that it was not from a lack of training or a process issue but a "people issue," explaining that operating room staff and SPS staff had responsibilities in recognizing nonconforming surgical instruments. The ADPCS shared that challenges exist at the facility in holding employees accountable.

The OIG concluded that facility SPS staff reprocessed surgical instruments with nonconformities that were used during a patient procedure. Surgical instrument nonconformities are a potential patient safety risk as instruments may not be able to be completely sterilized.[29] The surgical trays containing nonconformities found by the OIG during this inspection confirmed that the use of nonconforming surgical instruments during the spring 2024 procedure was not an isolated event. The OIG found that the chief of SPS and previous chief of SPS permitted SPS staff to continue reprocessing and use of nonconforming surgical instruments, which was inconsistent with facility policy and could have potential impacts on patient safety.

Operating Room Nurse Manager Did Not Provide Refresher Training

The OIG found the operating room nurse manager did not provide refresher training to operating room staff regarding identification of nonconforming surgical instruments after the nurse manager recognized the need for more rigid inspection of instruments.

One day after discovery of the nonconforming surgical instruments, the chief of SPS provided refresher training to SPS staff on the recognition, identification, and management of surgical instruments in poor condition. The nonconforming instruments from the rectal tray were used as an example for facility leaders and SPS staff to observe the nonconformities, and an educational poster was placed in the SPS preparation area. The OIG found no evidence that operating room staff received similar training. During an interview with the OIG, the operating room nurse manager denied knowledge of the nonconforming instruments in the rectal tray. However, the OIG reviewed VHA documentation that revealed the operating room nurse manager was aware eight days after the procedure, that nonconforming surgical instruments were used during the procedure and stated, "More rigid inspection of surgical equipment is needed." The operating room nurse manager told the OIG that there was "no discussion related to training" until facility leaders became involved in June 2024. When the OIG asked why training did not occur prior to June 2024, the operating room nurse manager responded

[29] The Joint Commission, *Quick Safety*, "Ensuring critical instruments and devices are appropriate for reuse," Issue 64, February 2022, accessed May 30, 2024, https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-64/.

- "my 'more rigid inspection' statement was less an indictment of the frontline staff's abilities and more of a question as to how leadership deprioritizes the important issues;"
- operating room staff "cannot conduct detailed, microscopic inspections in the few minutes they have between procedures and are limited to catching the more obvious issues: dull scissors, bent or broken instruments;"
- "there were multiple informal discussions where the OR [operating room] staff tried to figure out what could be done to catch and prevent these kinds of issues."

The OIG expected that after identification of the need for further inspection of RMDs, the operating room nurse manager would have ensured the operating room staff received refresher training on recognition, identification, and management of nonconforming instruments.

Facility Leaders Failed to Establish a Preventative Maintenance Program for Surgical Instruments

The OIG found no evidence that a preventative maintenance program for servicing surgical instruments existed prior to May 30, 2024, inconsistent with VHA policy established in March 2016.[30]

According to VHA policy, the chief of SPS is responsible for overseeing the RMD management program, which includes "programmed or preventive maintenance, sharpening, repair or replacement."[31] AAMI standards further clarify that servicing activities can be performed by facility or contracted staff and include RMD repair and routine and preventative maintenance.[32] Additionally, The Joint Commission guidance provides that staff should "establish effective maintenance and refurbishment processes to keep instruments in optimal condition."[33] The VISN CSPO is responsible for collaborating with facility leaders in "achieving the highest quality RMD outcomes," and identifying and mitigating associated risks.[34]

During an interview, the chief of SPS reported that in September 2023, concerns with the condition of surgical instruments were noted, along with the recognition that the facility did not have a preventative maintenance program. The chief of SPS also reported that the process to implement a preventative maintenance program was started by the development of a servicing contract, which was signed on May 30, 2024.

[30] VHA Directive 1116; The previous version of the SPS directive placed the responsibility for ensuring a preventative maintenance program upon facility directors, ADPCSs, and chiefs of SPS. VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016, rescinded July 17, 2023.

[31] VHA Directive 1116.

[32] ANSI/AAMI ST90:2017, *Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities*, 7.5.1.4, October 26, 2017.

[33] The Joint Commission, Ambulatory Buzz, *Is That Instrument Safe to Use on a Patient?* August 30, 2022.

[34] VHA Directive 1116.

In June and July 2024, the contract vendor conducted initial visits and identified over 800 surgical instruments as "beyond repair," including four instruments that were removed from the rectal tray.[35] According to the chief of SPS, the "beyond repair" instruments were removed from service and end users made the determination whether instruments needed to be replaced or deactivated and permanently removed from service.[36]

Figure 3. *Dental pick from restorative tray 45 prior to undergoing repair.*
Source: Preventative maintenance contract vendor, June 17, 2024.
Note: Example of surgical instrument deemed "extensive repairs" by preventative maintenance contract vendor during service. Red circle added by contract vendor indicating areas of nonconformity.

[35] "Beyond repair" indicates instruments that need to be removed from service.

[36] According to the chief of SPS, some of the 800 instruments deemed beyond repair were from active surgical trays and multiple were found in a soiled utility room.

Figure 4. *Dental pick from restorative tray 45 after undergoing repair.*
Source: Preventative maintenance contract vendor, June 17, 2024.
Note: Example of surgical instrument deemed "extensive repairs" by preventative maintenance contract vendor during service.

The chief of quality and patient safety and the acting ADPCS attributed the lack of a preventative maintenance program prior to May 2024 to "leadership turnover in both [SPS] and Nursing Leadership."

Documentation showed the former acting chief of SPS reported the lack of a facility preventative maintenance program through the VISN CSPO to the OSP, in the fall of 2021. The VISN CSPO told the OIG that the preventative maintenance program was not reviewed during prior VISN or OSP site visits.

The OIG concluded the facility did not have a preventative maintenance program until May 2024. While the chief of SPS identified the need to develop a preventative maintenance program, facility leaders and the VISN CSPO did not recognize this need prior to May 2024, which led to widespread surgical instrumentation being deemed "beyond repair" in June 2024. The combination of an absence of a preventative maintenance program along with facility leaders permitting the practice of reusing nonconforming surgical instruments increased the likelihood that patients were exposed to unnecessary safety risks.

2. Failure to Resolve Previous OIG-Identified Deficiencies

During this inspection, the OIG reviewed facility leaders' actions in response to SPS deficiencies identified in the March 2024 report. The OIG found that facility leaders failed to fully implement the CensiTrac instrument tracking system, address concerns with the CensiTrac coordinator's performance on implementation, and resolve concerns related to the intended use of an SPS conference and training room.

Facility Leaders' Continued Failure to Fully Implement CensiTrac

The OIG determined that facility leaders failed to fully implement CensiTrac, which is an open recommendation from the March 2024 OIG report.[37] Prior to the publication of the March 2024 OIG report, the Facility Director requested closure of the OIG recommendation to fully implement CensiTrac. However, upon review of the request, the OIG did not find adequate documentation to support the closure of the recommendation.

VHA uses the CensiTrac electronic instrument tracking system to track instruments from the beginning of reprocessing, through transporting, storing, and use.[38] CensiTrac helps improve patient safety, achieve sustainable SPS processes, and provide a means for analysis and quality improvement.[39] AAMI standards provide that "health care organizations shall identify" individual instruments through direct marking, bar coding, or color coding.[40] Marking individual instruments allows users the ability to track the instruments to specific patient cases.[41]

In an interview with the OIG, the CensiTrac coordinator reported that SPS staff began using CensiTrac to scan the decontamination process of surgical trays in December 2023. According to CensiTrac records, the rectal tray was last reprocessed on February 9, 2024. The tray underwent preparation and assembly phases; however, the decontamination phase was not documented.[42] During interviews, the assistant chief of SPS and the CensiTrac coordinator reported that staff completed the decontamination phase for the rectal tray but did not scan that step.

The OIG inspected the instruments in the rectal tray and found that some instruments were not marked or were improperly marked with a hand-engraved label of the manufacturer's name.

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[37] The OIG considers the CensiTrac Instrument Tracking System fully implemented when SPS staff routinely scan each surgical instrument through the full reprocessing cycle. For this to occur, each surgical instrument must be appropriately marked. VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*.

[38] VHA Directive 1116.

[39] U.S. Department of Veterans Affairs Office of Cyber Security, Security Reports and Oversight Management Service, *[Acquisition Review Module] ARM Security Policy Product Review CensiTrac*, May 21, 2018, accessed August 30, 2023, https://dvagov.sharepoint.com/:w:/r/sites/OITOIS/KnowledgeService/_layouts/15/Doc.aspx?sourcedoc=%7BA917DBD4-D48D-49BB-A378-728AD4958A82%7D&file=CensiTrac_v4.1.10.docx&action=default&mobileredirect=true&DefaultItemOpen=1 (This site is not publicly accessible).

[40] ANSI/AAMI ST90:2017*, Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities*, 7.5.3.1, October 26, 2017.

[41] "What are the current surgical instrument labeling techniques?" Censis, accessed July 25, 2024, https://censis.com/blog/what-are-the-current-surgical-instrument-labeling-techniques/.

[42] The reprocessing steps for RMD include decontamination (cleaning and inspection of soiled instruments), preparation (assembling and wrapping of instruments prior to sterilization), sterilization (removes all living microorganisms from instruments), and storage (reprocessed instruments are ready for use on patients and kept in an area to protect them from contamination.). VHA Directive 1116; ANSI/AAMI ST108:2023*, Water for the Processing of Medical Devices*, 3.8.1, August 18, 2023.

Improper engraving affects the instrument's surface, which could affect the ability of the instrument to be fully sterilized (see figure 5).[43]

Figure 5. *Rectal speculum from the rectal tray showing hand engraving of manufacturer's name "PRATT."*
Source: OIG, June 11, 2024.
Note: Photo taken by OIG staff during the site visit (after instrument was taken out of service). The yellow circle added by OIG staff indicates nonconformity.

In an interview with the OIG, the assistant chief of SPS stated individual instruments are not marked and scanned because CensiTrac contained incorrect, missing, and duplicate instrument information, and some information needed to be corrected. The OSP instrument tracking system program manager stated RMDs needed to be marked to demonstrate full CensiTrac system operations.

The chief of SPS told the OIG that after reprocessing a surgical tray, SPS staff deliver the surgical tray to the end user with a CensiTrac count sheet to ensure operating room staff have the expected instruments.[44] While on-site, the OIG audited five randomly selected surgical trays from the operating room sterile storage area; each tray included an SPS provided CensiTrac count sheet listing the instruments that should be in the tray.[45] Of the five surgical trays, the OIG

[43] Kyros Ipaktchi, et al., "Current Surgical Instrument Labeling Techniques May Increase the Risk of Unintentionally Retained Foreign Objects: A Hypothesis," Patient Safety in Surgery, no. 7, September 30, 2013, https://doi:10.1186/1754-9493-7-31.

[44] AORN eGuidelines+, "Guidelines for Perioperative Practice: Packaging Systems," accessed June 20, 2024, https://aornguidelines.org/guidelines/content?sectionid=173737249&view=book#229130163. The AORN guidelines state "instrument count sheets are used by perioperative teams for inventory control and for instrument counting during surgical procedures."

[45] Joan Spear, "Instrument Count Sheets and Set Reviews as Patient Safety Tools," *AORN Journal*, vol. 104, iss. 6, 588-292, https://doi.org/10.1016/j.aorn.2016.10.007. Count sheets are used as a tool to "ensure the correct instruments are in a set at the time of assembly" and should include specific information about the instruments including manufacturer and quantity. Correct count sheets contribute to patient safety.

found four trays included instruments that did not match what was listed on the count sheet.[46] These are examples of SPS staff not fully utilizing CensiTrac to ensure surgical trays have the correct surgical instruments, and that instruments were not properly marked as previously noted above.

Facility and SPS Leaders' Failed to Address Performance Concerns

The OIG found that facility and SPS leaders were aware of the CensiTrac coordinator's performance concerns but failed to address those concerns.

A responsibility of the CensiTrac coordinator is overseeing the system and instrument marking. The CensiTrac coordinator has been in the role since 2019 and SPS leaders told the OIG of performance challenges. Additionally, three healthcare oversight inspections, from 2022 through 2024, found CensiTrac was not fully implemented.[47] The VISN CSPO told the OIG of concerns with the CensiTrac coordinator's inability to implement CensiTrac functions effectively. These concerns were communicated to facility leaders.

The CensiTrac coordinator reported that previous chiefs of SPS did not provide sufficient training and support. It was only after the current chief of SPS arrived that training was offered to the CensiTrac coordinator. The chief of SPS confirmed the CensiTrac coordinator's performance was below the expected level and reported a lack of support from facility leaders regarding the CensiTrac coordinator's performance.[48] The ADPCS told the OIG that the prior chief of SPS and chief of SPS were advised to proceed with administrative action after documenting the performance concerns. However, the prior chief of SPS and chief of SPS failed to document the performance deficiencies, so no such action could be taken. The ADPCS attributed this failure to the lack of a handoff between the prior chief of SPS and chief of SPS, while also taking responsibility for the leadership failure.[49]

The OIG concluded that facility leaders did not fully implement CensiTrac despite VHA's requirements and the identification of this deficiency by multiple oversight bodies. The incomplete implementation of CensiTrac hampers the ability to track individual instruments and reprocessing history, which poses a risk to patient safety. The OIG determined that facility and SPS leaders were aware of the coordinator's performance deficiencies and the impact on CensiTrac implementation but failed to address those concerns. As of September 2024, the

[46] The differences included different manufacturers, additional instruments, and incorrectly sized instruments.

[47] The OIG, the National Office of Sterile Processing and the VISN CSPO conducted these inspections. VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*, Report No. 22-01315-90, March 6, 2024.

[48] Due to turnover in facility leadership positions, the ADPCS was the only leader with awareness of the coordinator's performance concerns who was continually in the same role during the relevant time frame.

[49] The chief of SPS confirmed no receipt of documentation related to the CensiTrac coordinator from the prior chief of SPS.

March 2024 OIG report recommendation related to the implementation of CensiTrac remained open. The OIG will continue to monitor until completed.[50]

SPS Conference and Training Room Purpose Remained Unresolved

The OIG found that facility leaders did not resolve the SPS staff conference and training room concern related to the March 2024 OIG report recommendation. The previous OIG report found SPS staff continued to use the conference and training room for lunch and breaks "and, because of its location, were still bringing their food and beverages through the sterile storage space" presenting "a risk for contamination and breach of environmental integrity in SPS."[51]

The OIG learned during interviews that the room's purpose had been changed to an SPS storage room. The VISN CSPO told the OIG that the change to the purpose of the room was an acceptable resolution to the finding. However, during the on-site inspection in June 2024, the OIG observed food and drink in the designated SPS storage room. The OIG reviewed the documentation provided by facility staff and found it did not confirm the testimonial evidence that the purpose of the conference and training room was changed. As of September 2024, this recommendation was still open, and the OIG will continue to monitor until completed.

Contributing Factors to Continued SPS Deficiencies

The OIG found that frequent changes in leadership positions, along with leadership failures as identified above, contributed to the continued SPS deficiencies discussed in this report.

The acting Facility Director acknowledged prior SPS deficiencies identified in the March 2024 OIG report and, despite progress in SPS, acknowledged the action plans to address the deficiencies were still in progress.[52] An example of one of the processes identified by the acting Facility Director as in need of improvement was for clinical service leaders to take ownership and responsibility for ensuring that correct RMDs are ordered. The acting Facility Director told the OIG that the reason for continued deficiencies in SPS was due to frequent changes in leadership positions, including the number of leaders serving in temporary roles. According to the ADPCS, from January 2022 through September 2023, the SPS chief position turned over four times, including the chief of SPS in position at the time of this inspection, who started employment at the facility in September 2023. On August 28, 2024, the assistant chief of SPS

[50] VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*.

[51] VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*.

[52] VA OIG, *Sterile Processing Service Deficiencies and Leaders' Response at the Carl Vinson VA Medical Center in Dublin, Georgia*.

left employment after less than two and a half months in the position.[53] At the time of the inspection, the ADPCS was administratively reassigned to the VISN as of summer 2024 and all members of the facility executive leadership team were serving in a temporary capacity.[54]

Additionally, the VISN CSPO reported concerns with facility executive leaders and the impact on SPS operations, specifically, siloed communication between SPS and operating room staff, and the decision to allow a "critical" position within SPS to remain unfilled.[55]

Conclusion

SPS and operating room staff failed to remove nonconforming surgical instruments from a rectal tray. Moreover, at the time of the inspection, the OIG found other surgical instruments in nonconforming condition. Contrary to policy, the reprocessing and use of nonconforming instruments was a permitted practice at the facility due to staff complacency, operating room staff's preference to receive complete trays, and an ongoing dispute as to which department—SPS or the operating room—had responsibility for replacing surgical instruments. The operating room nurse manager, after becoming aware of the nonconforming rectal tray instruments, did not provide refresher training to operating room staff regarding identification of nonconforming instruments. Facility leaders failed to establish a preventative maintenance program for surgical instruments until May 2024, which likely contributed to the widespread number of instruments with nonconformities.

Facility leaders failed to fully implement CensiTrac, which is an open recommendation from the March 2024 OIG report, and failed to address concerns with the CensiTrac coordinator's performance. The ADPCS and VISN CSPO were aware of the coordinator's performance deficiencies and the impact on CensiTrac implementation but failed to adequately address those concerns.

Facility leaders failed to resolve the March 2024 OIG report recommendation related to the conference and training room. Due to the open recommendation, the OIG did not issue another recommendation.

The OIG found that frequent changes in facility and SPS leadership positions, including long-term use of leaders in acting positions, contributed to the continued SPS deficiencies. The failures identified in this report, coupled with the prevalent, ongoing deficiencies, lack of

[53] According to the chief of SPS, the assistant chief of SPS position remained unfilled as of February 20, 2025.

[54] For purposes of this report, the OIG considers the facility director, associate director, chief of staff, and ADPCS positions as the facility executive leadership team. The OIG initiated a separate inspection focused on facility leadership and VISN responsibilities.

[55] The VISN CSPO identified the Lead Medical Supply Technician position as "critical."

oversight, and monitoring, increased the likelihood that patients were exposed to unnecessary safety risks.

Recommendations 1–5

1. The Carl Vinson VA Medical Center Director ensures applicable staff, such as Sterile Processing Services staff and end users of reusable medical devices, comply with procedures regarding the identification of and disposition of nonconforming surgical instruments.
2. The Carl Vinson VA Medical Center Director confirms operating room staff completes training regarding the recognition of and procedures for nonconforming surgical instruments.
3. The VA Southeast Network Director establishes a comprehensive strategy to review patients who may have been affected by the approximately 800 nonconforming surgical instruments to evaluate whether harm occurred, the need for patients to undergo testing or treatment, and the appropriateness of disclosures.
4. The VA Southeast Network Director evaluates whether administrative action is warranted for employees regarding Sterile Processing Services deficiencies at the Carl Vinson VA Medical Center, and takes action as appropriate.
5. The VA Southeast Network Director provides consultation and oversight to the Carl Vinson VA Medical Center's Sterile Processing Services to ensure implementation of facility-level action plans and sustainability of identified outcomes.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 13, 2025

From: Director, VA Southeast Network (10N7)

Subj: Healthcare Inspection—Continued Sterile Processing Services Deficiencies and Facility Leaders' Failures at the Carl Vinson VA Medical Center in Dublin, Georgia

To: Director, Office of Healthcare Inspections (54HL04)
Executive Director, Office of Integrity and Compliance (10OIC)

1. We appreciate the opportunity to review and comment on the OIG draft report, Healthcare Inspection—Continued Sterile Processing Services Deficiencies and Facility Leaders' Failures at the Carl Vinson VA Medical Center in Dublin, Georgia. I have completed a full review of the draft report and concur with the findings. We are committed to ensuring Veterans receive quality care that utilizes the high reliability pillars, principles, and values.

2. I concur with the recommendations and action plan submitted by the Carl Vinson VA Medical Center in Dublin, Georgia for recommendations 1-2. In addition, I concur with VISN 7's recommendations and action plan for recommendations 3-5.

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

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

(*Original signed by:*)

David M. Walker, MD, MBA, FACHE
Network Director

[OIG comment: The OIG received the above memorandum from VHA on February 13, 2025.]

VISN Director Response

Recommendation 3

The VA Southeast Network Director establishes a comprehensive strategy to review patients who may have been affected by the approximately 800 nonconforming surgical instruments to evaluate whether harm occurred, the need for patients to undergo testing or treatment, and the appropriateness of disclosures.

__X__Concur

____Nonconcur

Target date for completion: July 2025

Director Comments

The Veterans Integrated Service Network (VISN) Director is ensuring a comprehensive strategy is established for any needed clinical reviews for patients who may have been affected by the approximately 800 nonconforming surgical instruments. The strategy includes consultation and guidance from the VHA Clinical Episode Review Team (CERT) in coordination with subject matter experts from VHA Offices of Sterile Processing and Infection Control. A VISN-based team is overseeing the clinical review process and following to completion. Consultation with the CERT has been ongoing since August 1, 2024, including consultation on the lookback, a request for recommendations regarding the appropriateness and type of disclosures, testing and/or treatments indicated based on potential risks and/or identified harm to patients.

Recommendation 4

The VA Southeast Network Director evaluates whether administrative action is warranted for employees regarding Sterile Processing Services deficiencies at the Carl Vinson VA Medical Center, and takes action as appropriate.

__X__Concur

____Nonconcur

Target date for completion: March 2025

Director Comments

The VISN Director will work with Human Resources to determine if administrative actions are warranted for employees regarding Sterile Processing Services deficiencies at the Carl Vinson VA Medical Center. Any warranted actions will be taken as appropriate.

Recommendation 5

The VA Southeast Network Director provides consultation and oversight to the Carl Vinson VA Medical Center's Sterile Processing Services to ensure implementation of facility-level action plans and sustainability of identified outcomes.

__X__Concur

____Nonconcur

Target date for completion: July 2025

Director Comments

The VISN Director will ensure consultation and oversight implementation of facility-level action plans. The oversight of action plans and sustainability of identified outcomes will be monitored and tracked by the VISN Chief Sterile Processing Officer (CSPO) through monthly reviews (virtual/on-site). The VISN Chief Nursing Officer and CSPO will ensure open items are being actively worked and monitored for sustainability of closed actions. The VISN CSPO will provide status updates monthly to the VISN 7 Quality Patient Safety Committee, co-chaired by the Network Director.

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 8, 2025

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

Subj: Healthcare Inspection—Continued Sterile Processing Services Deficiencies and Facility Leaders' Failures at the Carl Vinson VA Medical Center in Dublin, Georgia

To: Director, VA Southeast Network (10N7)

1. We appreciate the opportunity to review and comment on the OIG draft report, Healthcare Inspection—Continued Sterile Processing Services Deficiencies and Facility Leaders' Failures at the Carl Vinson VA Medical Center in Dublin, Georgia. VA Carl Vinson VA Medical Center, Dublin Healthcare System, concurs with the recommendations and considerations in the report.

2. We appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans. The Carl Vinson VA Medical Center remains committed to ensuring our Veterans receive health care of the highest quality.

3. Carl Vinson VA Medical Center submits the attached action plan.

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

(*Original signed by*:)

Chandra Miller, MSN, RN, CNL
Interim Executive Director
Carl Vinson VA Health Care System
Dublin, VA

[OIG comment: The OIG received the above memorandum from VHA on February 8, 2025.]

Facility Director Response

Recommendation 1

The Carl Vinson VA Medical Center Director ensures applicable staff, such as Sterile Processing Services staff and end users of resuable medical devices, comply with procedures regarding the identification of and disposition of nonconforming surgical instruments.

__X__Concur

____Nonconcur

Target date for completion: May 2025

Director Comments

A local Standard Operating Procedure (SOP) and Medical Center Policy was developed regarding decommissioning, commissioning reusable medical devices into Censitrac. All sterile processing services (SPS) staff, dental, and operating/surgical staff have been trained to identify and how to dispose of nonconforming surgical instruments. A Steris representative also provided training to all SPS staff on nonconforming surgical instruments. A monthly report will be completed of how many nonconforming surgical instruments are identified by the end users and during reprocessing by SPS staff and the actions that are taken. Additionally, a multidisciplinary team, with SPS, Operating Room, and Dental representation, will conduct monthly random audits of 10 sterile package devices/sets each month. This process will be on-going and incorporated into the SPS Quality Management System activities. The monthly report will be a standing agenda item in the Reusable Medical Devices Oversight Committee and the Surgical Steering Committee. The Veterans Integrated Service Network (VISN) Chief Sterile Processing Officer (CSPO) will provide status updates monthly, for six months (August 2025), to the VISN 7 Quality Patient Safety Committee, co-chaired by the Network Director, and to the Office of Sterile Processing Health System Specialist, dedicated to VISN 7.

Recommendation 2

The Carl Vinson VA Medical Center Director confirms operating room staff completes training regarding the recognition of and procedures for nonconforming surgical instruments.

__X__Concur

____Nonconcur

Target date for completion: October 2024

Director Comments

A local Medical Center Policy was developed and implemented regarding decommissioning and commissioning reusable medical devices into Censitrac. All operating room staff have been trained to identify the process for disposing nonconforming surgical instruments and training will be provided upon hire for all new employees.

OIG Comments

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

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