DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Improvements in Sterile Processing Service and Leadership Oversight at the Edward Hines, Jr. VA Hospital in Hines, Illinois

HEALTHCARE INSPECTION | REPORT #22-00158-188 | JULY 7, 2022

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Edward Hines, Jr. VA Hospital (facility) in Hines, Illinois to assess allegations of deficient practices within the Sterile Processing Service (SPS) and failure of SPS leaders to provide adequate oversight, quality control, education, and training to SPS staff.

Due to the similar nature of the allegations that precipitated this review and prior allegations of SPS deficiencies reviewed by the OIG and facility in early 2021, the OIG assessed the implementation status of the facility's action plans from April 2021. The OIG found that the facility had implemented and sustained actions to address the previously identified deficiencies. During interviews, SPS leaders and a staff member explained the quality assurance measures in place in SPS, as well as process improvement actions implemented in response to prior concerns.

The OIG evaluated the new allegations of continuing issues with SPS reprocessing of reusable medical equipment. The OIG did not substantiate that dirty instruments were sent to the operating room and approved for use by SPS leadership, that endoscopes were not being cleaned properly, or that loaner trays were not reprocessed appropriately. The OIG found no reported deficiencies related to reusable medical equipment reprocessed for use in the operating room during the period of the current inspection.

In addition, the OIG did not substantiate that SPS leaders failed to provide adequate oversight, quality control, education, and training to SPS staff. SPS leaders had completed the required Veterans Health Administration (VHA) SPS certifications for their positions, and SPS leaders and education and training staff were sufficiently knowledgeable regarding the management of SPS and relevant standards.

The OIG also did not substantiate the allegation that SPS leaders and education and training staff lacked appropriate knowledge to provide staff training. SPS leaders and education and training staff implemented relevant training plans and assessed staff competencies in accordance with VHA policy.[1] SPS leaders conducted oversight of staff competencies per VHA policy.

Although the OIG noted instability within SPS leadership positions, facility leaders worked with Veterans Integrated Service Network (VISN) subject matter experts to ensure continuity of leadership in SPS when leadership vacancies existed. At the time of the inspection, facility leaders continued efforts to recruit a permanent candidate for the Chief of SPS position.

Over the course of interviews with leaders and staff, the OIG heard of challenges within SPS related to workplace culture. Based on the described challenges, along with the findings from this inspection, the OIG opined that individuals within SPS support the transitions in service

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

leadership and changes associated with ongoing quality improvement efforts at varying degrees. As such, the resulting workplace culture may have factored into unsubstantiated negative perceptions of service leadership.

The OIG did not substantiate that SPS standard operating procedures (SOPs) were chaotic and incomplete. The SPS SOPs were generally well-written and easy to follow with step-by-step instructions and illustrations. While the facility's overarching policy that addresses development of facility SOPs required updating to align with VHA policy and current facility practices, the OIG determined this finding did not rise to the level of a recommendation as a revised draft of the facility policy was in the process of review and approval.

The OIG determined that both the VISN and facility leaders maintained adequate oversight, identifying and taking actions in response to concerns, and providing support for quality improvement efforts within SPS at the facility.

The OIG made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report (see appendixes A and B). No further action is required at this time

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Contents

Abbreviations

ADPCS	Associate Director for Patient Care Services
ENT	Ear, Nose, and Throat
IFU	instructions for use
OIG	Office of Inspector General
RME	reusable medical equipment
SOP	standard operating procedure
SPS	Sterile Processing Service
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Edward Hines, Jr. VA Hospital (facility) in Hines, Illinois to assess allegations of deficient practices within the Sterile Processing Service (SPS) and failure of SPS leaders to provide adequate oversight, quality control, education, and training to SPS staff. Because the complainant alleged continuing concerns about deficiencies in SPS practices, which had been previously addressed by facility action plans submitted in response to a prior OIG inquiry, the OIG also reviewed the status of the facility's action plans to assess whether actions to address identified deficiencies had been implemented and sustained.

Background

Facility Operations

The facility is part of Veterans Integrated Service Network (VISN) 12 and includes six community care clinics. The Veterans Health Administration (VHA) classifies the facility as level 1a, highest complexity.[1] The facility offers a wide variety of clinical services including primary care, specialty services, and specialized clinical programs. From October 1, 2020, through September 30, 2021, the facility served 59,167 patients and had 473 beds consisting of 238 hospital beds, 25 domiciliary beds, and 210 community living center beds.

Sterile Processing Service

In VHA facilities, SPS has the primary responsibility to decontaminate or sterilize reusable medical equipment (RME) and instrumentation.[2] The Centers for Disease Control and Prevention guidelines emphasize that the sterilization of medical instruments is essential in preventing the transmission of infectious pathogens to patients. Failure to properly disinfect or sterilize equipment carries a significant risk for person-to-person transmission of infectious diseases.[3] Reprocessing is a term used to describe the steps involved in making a contaminated item reusable, including cleaning, testing, disinfection, or sterilization.[4] Staff responsible for

[1] VHA Office of Productivity, Efficiency, and Staffing. The Facility Complexity Model classifies VHA facilities as levels 1a, 1b, 1c, 2, or 3, with level 1a being the most complex and level 3 being the least complex. A level 1a facility has high-volume, high-risk patients; the most complex clinical programs; and large research and teaching programs.

[2] VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016. RME is "intended for repeated use on different patients with appropriate decontamination and other processing between uses."

[3] Centers for Disease Control and Prevention, "*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008,"* updated May 2019, accessed November 8, 2021, https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

[4] VHA Directive 1116(2).

reprocessing RME must be trained according to device-specific instructions for use (IFUs) and demonstrate competency in the proper reprocessing procedure for each item.[5]

Prior OIG Reports

In August 2020, the OIG published a report, *Comprehensive Healthcare Inspection of the Edward Hines, Jr. VA Hospital in Hines, Illinois*. During that inspection, the OIG determined that "[t]he medical center met many of the requirements for the proper operations and management of reprocessing RME. However, the OIG identified deficiencies with quality assurance monitoring; reprocessing and storage area physical inspections; and staff training, competency and ongoing education." The OIG found that "SPS staff tested less than 10 percent of endoscopes to ensure bioburden was removed after reprocessing. This resulted in a lack of assurance that appropriate and safe reprocessing had been performed." The OIG made one recommendation related to SPS, that "[t]he Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that at least 10 percent of reprocessed endoscopes are tested for bioburden."[6] The recommendation was closed at the time of the current inspection.

Prior Deficiencies

The OIG received prior allegations related to the facility SPS in December 2020 and referred the allegations to facility leaders in February 2021 for further review. Facility leaders examined the allegations, which cited the following: SPS sent dirty instruments to clinics causing delays in patient care and patient safety risks, nursing leadership requested changes to patient safety reports about RME concerns, and instruments were poorly handled in SPS resulting in a year's cost of over $100,000 for repairs and replacements.[7] Facility leaders partially substantiated the allegations and responded to the OIG with action plans in April 2021 to address the identified

[5] VHA Directive 1116(2). Facility Policy Memorandum 578-09-002-009 (R-4), *Standard Operating Procedures for Reusable Medical Equipment (RME)*, May 8, 2019.

[6] VA OIG, *Comprehensive Healthcare Inspection of the Edward Hines, Jr. VA Hospital in Hines, Illinois,* Report No. 20-00069-222, August 25, 2020.

[7] VHA Directive 1320, *Quality Management and Patient Safety Activities that can Generate Confidential Records and Documents*, July 10, 2020. Patient safety reports refer to a mechanism for "reporting, review or analysis of incidents involving patients that cause harm or have the potential for causing harm."

deficiencies.[8] Following a review of the action plans and supporting documentation, the OIG determined that the facility action plans sufficiently addressed the deficiencies and closed the case.

Allegations and Related Concerns

On August 20, 2021, the OIG received a complaint alleging ongoing deficiencies in SPS practices, and a failure of leaders to address the concerns. During an interview, the OIG clarified the allegations with the complainant. Specifically, the complainant alleged:

- SPS staff sent dirty instruments to the operating room and SPS leadership approved them for use.
- Endoscopes are not being cleaned in accordance with the manufacturer's IFU.
- Loaner instrument tray instruments are not being cleaned in accordance with the manufacturer's IFU.
- SPS leaders lack the knowledge and appropriate skills for managing SPS.[9]
- SPS education and training staff do not know the necessary information to train staff.
- SPS standard operating procedures (SOPs) are chaotic, incomplete, and are approved by leaders despite the deficiencies.[10]

The OIG recognized that the allegations related to instruments that were not properly cleaned were similar to those reviewed by the OIG and facility earlier in the year. Due to the allegation of ongoing deficiencies in SPS practices and the associated risks, the OIG opened an inspection to review the status of the facility action plans previously submitted and to evaluate the new allegations. The OIG identified the period for review as starting in April 2021 in order to include

[8] Facility leaders' review of the January 2021 allegations found that 40 patient safety reports regarding RME in surgical clinics and operating rooms were submitted in fiscal year (FY) 2021, but found no harm to patients and no procedures cancelled as a result of the concerns identified in those reports. Facility leaders also found that a former nursing leader had requested certain RME-related patient safety reports, submitted by a staff member in the Ear Nose and Throat (ENT) clinic, be rejected. The requests noted concerns that the patient safety reports were being utilized as a communication tool in lieu of direct discussion about concerns between service staff. However, facility Patient Safety and Quality Management staff refused the request and the patient safety reports remained unchanged in the system. The review substantiated a total of 191 missing instruments and confirmed that FY 2021 equipment repair costs were greater than $100,000, but also noted that the costs were not significantly different than the costs incurred for equipment repairs over the previous five years.

[9] Specifically, the complainant alleged that SPS leaders "don't know what SPS is or how it functions," and facility leaders "put unskilled nurses to take over SPS." For the purpose of the current inspection, the OIG considered SPS leaders to include the Acting Chief of SPS and the Deputy Chief of SPS.

[10] *Merriam-Webster.com Dictionary*, "standard operating procedure," accessed February 12, 2022, https://www.merriam-webster.com/dictionary/standard%20operating%20procedure. SOPs are established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations.

an assessment of the facility's performance following the implementation of facility action plans to address previously acknowledged deficiencies.

Scope and Methodology

The OIG initiated the inspection on October 14, 2021, and clarified the allegations during an interview with the complainant on November 17, 2021. The OIG conducted virtual interviews between December 7, 2021, and February 1, 2022. An on-site visit to allow for direct observation of SPS practices was initially planned, but subsequently canceled due to concerns about the rapid spread of a COVID-19 variant and increasing COVID-19 cases.

The OIG interviewed the VISN 12 Quality Management Officer, VISN 12 SPS/RME Program Manager, Facility Director, Associate Director for Patient Care Services (ADPCS), Chief of Staff, Chief of Surgery, and current and former acting and permanent SPS Chiefs. The OIG also interviewed leadership and staff from SPS; Surgery; the Ear, Nose, and Throat (ENT) clinic; Quality Management; and Patient Safety.

The OIG reviewed relevant VHA directives; facility policies; SOPs; IFUs; meeting minutes of the RME, Infection Control, and Surgical Work Group committees; SPS in-service training; Human Resources and personnel documents; issue briefs and quality assurance reports; internal and external quality reviews; SPS staff training records; and Infection Control data. The OIG also reviewed relevant external standards.

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 substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

Inspection Results

Due to the similar nature of the allegations that precipitated this review and those reviewed by the OIG and facility in early 2021, the OIG assessed the implementation status of the facility's action plans from April 2021 related to identified SPS deficiencies. The OIG found that the facility had implemented and sustained actions to address the deficiencies identified in 2021.

The OIG then assessed the subsequently alleged deficiencies in SPS practices and failures of SPS leadership, and reviewed performance following implementation of the April 2021 action plans. The OIG did not substantiate continuing concerns and found that the cumulative quality improvement actions taken by the facility had addressed and resolved the deficiencies. Additionally, the OIG did not substantiate the allegations regarding SPS service leadership; SPS leaders had relevant qualifications and were actively engaged in the service's quality improvement efforts. The OIG also reviewed facility leaders' and VISN oversight of SPS-related concerns and found that leaders were engaged, knowledgeable, and actively supported quality improvement processes.

1. Status of Facility Action Plans

The OIG's review confirmed that the facility implemented the action plans submitted in April 2021 to address previously identified deficiencies.

Actions Addressing Prior SPS Reprocessing Concerns

During interviews, SPS leaders and a staff member detailed quality assurance measures in place in SPS, as well as implemented process improvement actions. For example, a quality assurance medical supply technician described a practice of verifying reprocessed loads to ensure that reprocessing parameters met manufacturer IFUs for the devices, as well as a process of auditing all clinical RME prior to distribution to clinical areas. The Deputy Nurse of SPS described several specific process improvement actions implemented in SPS, including the use of custom, color coded tags with reprocessing data for scopes; equipment to reduce instrument handling during reprocessing; and containers instead of wrappings to reduce risk of damage to instruments during reprocessing. Additional efforts included reorganizing instrument trays, changing the type of cloth used to eliminate potential transfer of fibers to instruments, implementing new indicators to provide clearer visual confirmation of sterility following reprocessing, and changing case cart storage to improve identification of items within the carts. Additional staffing, equipment upgrades, and reorganization of some SPS space and workflows were also identified as implemented improvements. The Deputy Nurse of SPS described the service's commitment to continuing process improvement efforts and ensuring that SPS reprocessing of equipment meets the needs of clinical end users and supports safe patient care.

Actions Addressing Prior RME-Related Patient Safety Concerns

In reviewing RME issues, Patient Safety staff reported that none of the instruments with identified concerns were, in fact, used in patient care, as problems were detected prior to use. The Facility Director reported that the facility implemented additional training on RME reprocessing. In addition, facility leaders established biweekly meetings between service leaders to facilitate communication between SPS and clinical end users about RME issues, and the RME committee began tracking reported issues. The Facility Director also reported that the Patient Safety staff provided reeducation for staff on patient safety event reporting.

Actions Addressing Prior Lost and Damaged RME Concerns

Facility action plans also addressed concerns about missing and damaged equipment and included conducting an inventory of instruments in January 2021. SPS leaders and staff confirmed that the facility implemented CensiTrac, an "electronic tracking and data management system for surgical instruments" to assist in inventory management and quality assurance processes.[11] Facility SPS includes two staff members with RME Coordinator roles; the OIG was told during an interview that the Medical Supply Technician RME Coordinator oversees RME maintenance and works with clinical services and vendors to address equipment needs. The Medical Supply Technician RME Coordinator reported that implementation of CensiTrac allowed SPS to run maintenance reports and identify instruments missing from trays, which had assisted with reducing the rate of trays with missing items. In addition, the facility RME committee minutes documented a review of reports on RME repair costs and equipment requests.

The OIG team concluded that the facility had implemented the action plans submitted in April 2021, and that the actions addressed the identified deficiencies.

2. Alleged Deficiencies in SPS Practices

The OIG then evaluated the new allegations of continuing issues with SPS reprocessing of RME. The OIG did not substantiate that dirty instruments were sent to the operating room and approved for use by SPS leadership, that endoscopes were not being cleaned properly, or that loaner instrument trays were not reprocessed consistent with the SPS SOP for vendor loaned RME.

VHA policy requires facilities to ensure that RME is reprocessed in accordance with current manufacturers' IFUs. Personnel involved in RME reprocessing must be trained and the staff

[11] VA Technical Reference Model, "CensiTrac InstrumenTrac," accessed January 18, 2022, https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=8145. VHA Deputy Under Secretary for Health for Operations and Management memo, "Instrument Tracking Systems for Sterile Processing Services," January 1, 2019. "All facilities with SPS are required to deploy ITS [Instrument Tracking System] for instrument level instrument tracking." CensiTrac is the "defacto standard ITS [Instrument Tracking System] that all facilities shall utilize."

training, as well as competency in reprocessing procedures, must be validated. VHA policy also requires each facility to establish a quality assurance program for RME reprocessing.[12]

Dirty Instruments Allegedly Sent to the Operating Room and Approved for Use by SPS Leaders

The OIG conducted interviews with end users of RME in the operating room and ENT clinic, as well as SPS staff and leaders, and did not substantiate the allegation that dirty instruments had been sent to the operating room and approved for use by SPS leadership.[13] Leaders and a staff member from the operating room confirmed that there had not been an issue with the cleanliness of instruments within the timeframe of this review. Similarly, an ENT leader reported no recent issues with bioburden on instruments in the operating room.[14] An SPS leader and a staff member stated they were unaware of any such concerns occurring following implementation of action plans submitted in April 2021. Additionally, SPS leaders and staff provided examples detailing quality improvement actions that had been undertaken in response to past concerns, and explained changes made in SPS processes, which had resolved those issues.[15] The VISN SPS/RME Program Manager reported to the OIG that the facility had developed a strong quality assurance approach in SPS that includes in-depth inspections of RME packaging before delivery to the end-user.

Through a review of RME-related patient safety reports, the OIG noted no concerns were submitted after August 2021. The OIG found quality improvement actions had been implemented, which included manufacturer consultation on the SPS cleaning process and ordering of new scopes.

Endoscopes Allegedly Not Cleaned Properly

The OIG team did not substantiate the allegation that SPS staff failed to clean endoscopes properly. Concerns had been previously raised in 2020 by staff from the ENT clinic, which had resulted in SPS leaders conducting a review of endoscope reprocessing procedures and requesting consultation from the manufacturer of the endoscopes. During interviews, the OIG was told that the manufacturer representatives' direct observation found no deficiencies in the reprocessing of the endoscopes. In interviews with SPS leaders and a staff member, the OIG was

[12] VHA Directive 1116(2).

[13] ENT staff were interviewed because prior RME-related concerns included issues with SPS reprocessing of endoscopes utilized during ENT procedures. The new allegations cited endoscopes not being cleaned in accordance with the manufacturer's IFU.

[14] VHA Directive 1116(2). Bioburden is the number of bacteria found on reusable medical equipment which renders the item contaminated and not able to be used on a patient.

[15] Examples of quality improvement actions taken by SPS include changing the color of sterilization tags from green to white for easier readability, changing to clear case carts for quicker identification and less physical engagement, using a triplication sheet for loaner trays, and simplifying the case containerization process.

told that a process was in place to ensure multiple levels of equipment inspection before sending RME out for use. In response to the reported concerns, the acting SPS leader told the OIG they had implemented and maintained a 100 percent check of all reprocessed endoscopes exceeding the standard established in VHA policy that requires only 10 percent to be checked for quality assurance.[16] Facility staff from Patient Safety and Quality Management told the OIG team there had been a "dramatic reduction" in the volume of issues related to endoscopes reported by ENT staff, and stated no awareness of endoscope-related issues within the timeframe of the current review. Similarly, VISN 12 and facility leaders had awareness of the implemented quality improvement processes, and did not identify any current problems with improper cleaning of endoscopes.

The OIG did not find that endoscopes were not being cleaned properly.

Loaner Instrument Trays Allegedly Reprocessed Incorrectly

The OIG team did not substantiate the allegation that loaner instrument trays were not reprocessed correctly.[17] During interviews, leaders from the operating room and ENT clinic did not identify any issues with the incorrect reprocessing of loaner instrument trays by SPS. An operating room staff member reported one incident of a loaner tray being incorrectly labeled, and a previous Chief of SPS acknowledged an earlier problem with late receipt of loaner instrument trays, which prompted SPS staff to follow up with Patient Safety staff. The OIG's review of patient safety reports confirmed entries related to the late receipt of loaner trays, as mentioned by the previous Chief of SPS, but did not identify any reports of incorrectly reprocessed loaner trays.

VHA and facility policy require loaner trays to be delivered to SPS at least 48 working hours before use to ensure time for proper reprocessing.[18] Facility staff from Patient Safety confirmed that sometimes loaner instrument trays were not received in SPS prior to the 48-hour window as required. In response, according to SPS leaders, the current SPS practice is to stock extra vendor-supplied loaner instrument trays which allows SPS to reprocess instruments if issues are identified and still be able to provide a different instrument tray in order to avoid potential delays in clinical procedures.

The OIG did not find that loaner instrument trays were incorrectly reprocessed.

[16] VHA Directive 1116(2).

[17] VHA Directive 1116(2). Loaner instrument trays refers to instrumentation that the facility does not own but borrows for use. Vendors provide loaner instrument trays to the facility and SPS reprocesses the instrumentation to ensure appropriate sterilization prior to use.

[18] VHA Directive 1116(2). Facility SOP VHA-V12-578-IL-SOP-9499F, *Standard Operating Procedure for SPS Vendor Loaned Reusable Medical Equipment*, November 19, 2019.

3. Alleged Failures in Oversight, Quality Control, Education, and Training

The OIG found that SPS leaders and education and training staff were knowledgeable about SPS requirements, processes, and quality improvement efforts. Additionally, the OIG did not substantiate that SPS leaders failed to provide adequate oversight, quality control, education, and training to SPS staff. Although the OIG found some instability within SPS leadership positions, SPS leaders had adequate knowledge and were working with facility and VISN leaders to ensure continuous improvement.

SPS Leaders' Certifications and Knowledge of SPS Processes

The OIG did not substantiate the allegation that service leaders lacked the knowledge or appropriate skills for managing SPS.

The OIG found that SPS leaders had completed the required SPS certifications for their positions and identified no substantive education or knowledge gaps. The SPS leaders were knowledgeable about the requirements and quality assurance processes for management of SPS, including relevant standards such as those developed and disseminated by the Association for the Advancement of Medical Instrumentation and Association of periOperative Registered Nurses.[19]

VHA requires all new SPS employees to complete "Level 1" SPS training within 90 days of being hired.[20] Additionally, the Chief of SPS is required to complete the " Level 2" SPS certification within 6 months from the time of appointment, or obtain a SPS certification through a professional organization such as the International Association of Healthcare Central Service Materiel Management or the Certification Board for Sterile Processing and Distribution.[21] Level 2 certification is encouraged, but not required, for other SPS positions.[22]

[19] The Association for the Advancement of Medical Instrumentation "is a nonprofit organization that develops and publishes standards detailing the proper production quality for medical instruments and the procedures in which they are used." The Association of periOperative Registered Nurses "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." VHA Directive 1116(2). The Association for the Advancement of Medical Instrumentation "standards will be applied to critical and semi-critical RME management." The Association of periOperative Registered Nurses "guidelines will support and enhance all recommended standards which relate to instrument processing and infection control practices."

[20] VHA Directive 1116(2).

[21] VHA Directive 1116(2). The International Association of Healthcare Central Service Materiel Management, subsequently renamed the Healthcare Sterile Processing Association, promotes "patient safety worldwide by raising the level of expertise and recognition for those in the Sterile Processing profession." VHA Directive 1116(2). The International Association of Healthcare Central Service Materiel Management "guidelines will support and enhance all recommended standards which relate to instrument processing and infection control practices."

[22] VHA Directive 1116(2).

Both the Acting Chief of SPS and Deputy Nurse of SPS completed their "Level 1" training within 90 days of appointment. Although not required, the Deputy Nurse of SPS also completed the "Level 2" certification. The Acting Chief of SPS did not obtain the "Level 2" certification within six months of appointment; however, during interviews, the Acting Chief of SPS clarified that the acting role was intended to be a short-term assignment while hiring efforts for a permanent Chief were underway, but was extended due to challenges in filling the position. VHA policy does not address the training requirement for those in an acting capacity.[23] According to the VISN SPS/RME Program Manager, those in an acting role have historically not had the same training requirement because of the short-term nature of the temporary assignment, but generally complete at least "Level 1" training.

SPS Staff Training and Oversight of Staff Competencies

The OIG did not substantiate the allegation that SPS leaders and education and training staff lacked appropriate knowledge to provide staff training. The OIG found that SPS leaders and education and training staff implemented relevant training plans and assessed staff competencies in accordance with VHA policy.

SPS Staff Training

VHA requires that "all SPS employees must participate in the continuing education program."[24] VHA policy specifies that the technical aspects of SPS are the focus of monthly in-service sessions and computer-based training is an acceptable method.[25] An annual training plan must be developed and documentation maintained for in-service sessions, including a brief description of training content and objectives, and an attendance roster.

During interviews with the OIG, SPS leaders and education and training staff provided information about SPS's training program which included in-service trainings, computer-based learning modules in the Talent Management System, just-in-time trainings, staff meetings, and competency checks.[26] The SPS Educator, who is responsible for the development of the SPS training plan, detailed a structured plan for orienting and training new staff on SPS processes, as well as coordinating ongoing education for the department. The OIG reviewed documentation from monthly in-service trainings, and found that the trainings included education on technical aspects of SPS such as sterility, quality assurance standards, and reprocessing endoscopes. In addition to the scheduled trainings, SPS leaders reported that SPS staff were encouraged to

[23] VA Handbook 5005/61 Part IV Chapter 3, *Staffing*, November 20, 2012. "A detail is the temporary assignment of an employee to a different set of duties for a specified period of time."

[24] VHA Directive 1116(2).

[25] VHA Directive 1116(2).

[26] VA Directive 0004, *Education and Learning Delivery System*, April 20, 2012. The Talent Management System is the VA central software system used for online training for employees.

contact SPS leads, quality assurance technicians, supervisors, or educators for additional questions or retraining. The SPS leaders stated that assistance is available after hours as well as during normal business hours. The VISN SPS/RME Program Manager reported that the facility showed substantial improvements in SPS education, documentation of training, and management of competencies over the past half year. The improvements noted were attributable to the action plans implemented in April 2021, as well as action plans associated with prior internal and external reviews and ongoing quality improvement efforts implemented by SPS leaders.

SPS Staff Competencies

The OIG found that SPS leaders conducted oversight of staff competencies per VHA policy. SPS leaders reported that staff competencies were assessed through a variety of methods including verbalization, observation, and hands-on return demonstration.[27]

VHA and facility policy requires individuals assigned to SPS reprocessing duties to be trained and competent.[28] Competencies reflect the knowledge, skills and abilities required to work independently within SPS. The competency assessment process is completed when employees begin work in SPS, throughout their orientation, and regularly during their employment in the department. VHA requires that "those assessing competencies must be competent themselves with the task/process for which they are validating competence."[29] The SPS Chief, Assistant SPS Chief, SPS supervisors, educators, or other designated staff members can perform competency assessments. Competency verification methods include return demonstrations, observation, and verbalization of the processes.

Due to the allegations received about endoscope reprocessing, the OIG reviewed competency documents for reprocessing endoscopes. The OIG confirmed the facility's use of verbalization, simulation, return demonstration with direct observation, and demonstration being the most common methods of ensuring competency. The OIG also confirmed that staff who validated competencies were knowledgeable to perform the assessment.

Competencies were most often validated by medical supply technician supervisors, leads, and training staff, who all had established competencies. Additionally, the SPS Nurse Educator assessed competencies of the training staff, RME Coordinator, and quality assurance medical supply technician. While the SPS Educator is not directly responsible for reprocessing of RME,

[27] "A Guide to Competency Development for Healthcare Facilities", Steris University, accessed February 23, 2022, https://university.steris.com/in-service-tools/competency-docs/AGuidetoCompetencyDevlopmentforHealthcareFacilitiesM10712EN.pdf. "Return demonstration is an educational technique in which an employee demonstrates what they have just been taught or had demonstrated to them."

[28] VHA Directive 1116(2). Facility Policy Memorandum 578-09-002-009 (R-4).

[29] VHA Memorandum, *Competency Assessment for Employees Reprocessing Critical and Semi-critical Reusable Medical Equipment*, May 27, 2020.

the OIG learned that the SPS Educator participates in the process of developing and reviewing the SOPs on which SPS staff competencies are based. The OIG determined the SPS Educator had working knowledge of the SOPs, and therefore would be "familiar with the process," per VHA policy, and competent to assess competencies of others. [30]

Leadership Turnover and Workplace Culture

During the course of the review, the OIG noted instability within SPS leadership positions and with the Associate Director of Patient Care Services position, who has responsibility for facility-level oversight of the service. For example, the Chief of SPS position had five different people detailed into the acting role since December 2019, with one permanent Chief who exited the position in March 2021. However, the OIG heard during interviews that facility leaders worked with VISN subject matter experts to ensure continuity of leadership in SPS when leadership vacancies existed. The OIG also learned during interviews, and a review of personnel documents provided by the facility, that VISN subject matter experts, SPS staff from another VHA facility, and internal nursing leaders had served in the role of Acting Chief of SPS. At the time of the inspection, facility leaders continued efforts to recruit a permanent candidate for the Chief of SPS position.

Facility and VISN leaders reported that current SPS leaders were meeting expectations and described continuing quality improvements in the department. While the OIG heard reports from some staff that certain SPS leaders did not have specialized experience in SPS, VHA does not have mandatory experience requirements and facility leaders have the ultimate responsibility for the recruitment and selection of SPS leadership positions. As discussed above, the OIG determined that SPS leaders were knowledgeable about SPS processes, standards, and training methods, and that SPS leaders met VHA SPS certification requirements.

In addition, throughout interviews with SPS leaders and staff, the OIG heard of challenges within SPS related to workplace culture. Based on the described challenges, along with the findings from this inspection, the OIG found that individuals within SPS support the transitions in service leadership and changes associated with ongoing quality improvement efforts at varying degrees. As such, the resulting workplace culture may have factored into unsubstantiated negative perceptions of service leadership.

4. Alleged Deficiencies in Facility SPS SOPs

The OIG did not substantiate that facility SPS SOPs were chaotic and incomplete. The SOPs were generally well-written and easy to follow with step-by-step instructions and illustrations.

[30] VHA Directive 1116(2).

However, the OIG did note that the facility's overarching policy that addresses the development of RME-related SOPs required updating to align with VHA policy and current facility practices.

Facility SPS SOPs are intended to provide detailed, step-by-step instructions for reprocessing of RME based on the manufacturer's IFU. The RME Coordinator told the OIG that SOPs are revised, as needed, to incorporate facility-specific equipment, chemicals and supplies.[31] According to VHA policy, the Chief of SPS is responsible for "developing SOPs and competency assessments" and ensuring that they are "kept up to date, reviewed at least every 3 years and updated when there is a change in process or a change in the manufacturer's IFU." SOPs must be readily available to all staff at all times and written in plain language.[32] Facility policy also requires the Chief of SPS to ensure device-specific SOPs are listed on the SPS SharePoint, and posted in all areas where the devices are reprocessed, as well as ensure that there is a process in place to provide document control and dissemination of revisions.[33] SOPs are reviewed and signed by the Associate Director of Patient Care Services and the Chief of SPS.

SOP and IFU Alignment

Due to the allegations received and the volume of prior patient safety reports specifying concerns about endoscope reprocessing, the OIG conducted a review of facility SOPs and IFUs for endoscope reprocessing. The OIG found that the SPS SOPs provide detailed directions regarding the proper cleaning, disinfection, and sterilization of endoscopes, and generally match the manufacturer's IFUs. During interviews with the OIG, two SPS staff members reported that SOPs do not align with the corresponding IFUs, but were unable to provide specific examples. Other SPS staff members reported that SOPs have improved, are easier to read, and include illustrations and step-by-step instructions. One SPS staff member stated, "if you have no SPS experience and you came here and said please pull up this SOP for this instrument, I would like to attempt to process it; I would put money on it that you would be able to process it, slowly—but it's so detailed that you would be able to do it." SPS staff told the OIG they are able to access SOPs through the facility's intranet site and SharePoint site, have hard copies printed in reprocessing areas for contingencies, and have access to OneSource, an online repository of manufacturers' IFUs.

During interviews with the OIG, a VISN leader, SPS leaders, and SPS staff described the facility's process for developing SPS SOPs, which involves the SPS leaders developing and

[31] Facility Policy Memorandum 578-09-002-009 (R-4).

[32] VHA Directive 1116(2).

[33] Microsoft SharePoint is a web-based platform used for sharing files and information.

reviewing the SOP prior to sending it to facility leaders for review and final approval.[34] The VISN Deputy Chief Nursing Officer advised that this process is similar to other policy development processes in which the facility leaders are not the subject matter experts, but rather ensure consistency and quality assurance within facility policies.

Facility Policy

The OIG found that the facility has a process in place for the development and approval of SOPs for reprocessing RME; however, the facility policy for SPS SOP development required updating.

During a review of facility policies and SOPs, the OIG noted inconsistencies in the facility policy guidance related to the frequency of SOP reviews and SOP authorization dates.[35] The required SOP review cycle was unclear as it varied within the facility policy. The VISN SPS/RME Program Manager reported similar concerns and reported requesting the facility policy be updated to reflect current National Program Office for Sterile Processing guidance. The OIG noted that dates of approval listed on SOPs did not match the dates of the ADPCS authorizing signature, which the RME Coordinator attributed to delays in the electronic signature process.

The ADPCS and RME Coordinator informed the OIG of a plan to update facility policy to reflect current practices for SOPs, and the ADPCS reported a plan was in place to review the policy. Due to the plans the facility had already implemented, the OIG determined a recommendation to be unnecessary.

5. Facility and VISN Leaders' Oversight

The OIG found that facility and VISN leaders maintained oversight and provided support for quality improvement efforts within SPS. Per VHA policy, VISN directors are responsible for appointing and maintaining a VISN SPS Management Board that is responsible for the "oversight of SPS and all reprocessing of critical and semi-critical RME at VISN facilities," and ensuring that VA medical Facility Directors comply with the procedures and responsibilities

[34] The OIG heard during interviews with SPS leaders and staff that SPS SOP development process at the facility begins with the RME Coordinator writing the SOP based on the manufacturer's IFU. It is then reviewed by the Deputy Nurse for SPS, Quality Assurance staff, SPS Registered Nurse Educator, and RME Medical Supply Technician Instrument Coordinator. Following that review, the SOP is sent to Infection Control staff and the Chief SPS, and then finally to the ADPCS for final signature.

[35] Facility Policy Memorandum 578-09-002-009 (R-4). The facility policy included language stating that "SOPs will be reviewed annually and/or when new manufacturer's guidelines are issued, whichever occurs first" within one section of the document, but in other sections referred to "tri-annual/ annual review" of SOPs and the process for "Tri-Annual and/or Annual Review or Revision" of SOPs. VHA Directive 1116(2). The Chief of SPS is responsible for "[e]nsuring that all SOPs are kept up-to-date, reviewed at least every 3 years and updated when there is a change in process or a change in manufacturer's IFU."

outlined within the policy. The ADPCS has oversight, organizational responsibility, and leadership of facility SPS operations.[36]

During interviews with the OIG, VISN leaders identified leadership instability as an organizational risk and challenge. Recognizing stability in key leadership roles as an important component of ensuring continuity of quality improvement efforts, as well as effective partnerships among key support services, VISN leaders reported monitoring leadership vacancies filled by acting roles in both service-level and facility leadership.

At the time of the OIG's review, the Facility Director reported to have been in the position for less than two years and acknowledged that deficiencies in SPS were present at the time of assuming that role. In an interview with the OIG, the Facility Director spoke of his knowledge and involvement related to the external reviews of SPS operations and collaboration with VISN leaders to implement quality improvement efforts to address deficiencies. The Facility Director also shared positive assessments of the progress made by SPS since that time. The facility's ADPCS, who had been in the position for less than nine months at the time of the OIG's review, also spoke in detail about challenges with SPS and described actions taken to support ongoing quality improvement efforts. For example, the ADPCS organizationally re-aligned the Chief Nurse for Surgery under the same reporting chain as the Chief Nurse for SPS to improve communication processes between SPS and clinical service end users of RME. The Associate Director of Patient Care Services also noted working with human resources to upgrade the position and offer incentives to attract well qualified candidates for the permanent Chief of SPS posting. The VISN SPS/RME Program Manager attributed improvements in SPS service training, tracking, and documentation of competencies in part to stabilization in facility-level SPS leadership under the new permanent ADPCS, following a succession of temporary acting roles.

During interviews with VISN, facility, and SPS leaders, the OIG team was consistently told that the VISN SPS/RME Program Manager was involved in oversight and ongoing improvement efforts in the facility's SPS. The OIG found that the VISN SPS/RME Program Manager worked closely with facility leaders to identify and track deficiencies and implement system changes to address identified concerns. The VISN SPS/RME Program Manager described activities supporting SPS leaders throughout the VISN, including weekly to biweekly meetings with SPS Chiefs, on-site visits as needed, and facilitation of mentoring and collaboration between service chiefs across facilities. VISN leaders also coordinated with human resources to support personnel actions for the department after being advised of challenges with this issue.

VISN, facility, and service leaders acknowledged continuing challenges for SPS, including stabilizing service-level leadership and addressing personnel and cultural factors. Facility and VISN leaders also acknowledge that, while the aging space currently used for SPS operations

[36] VHA Directive 1116(2).

introduced several challenges, efforts had been made to improve the space and equipment to support the mission of SPS.

In conclusion, the OIG determined that both the VISN and facility leaders maintained adequate oversight, identifying and taking actions in response to concerns related to SPS at the facility.

Conclusion

The OIG reviewed the implementation status of the facility's April 2021 action plans related to identified SPS deficiencies and concluded that the facility implemented the action plans and that the actions addressed the identified deficiencies. During interviews, SPS leaders and a staff member explained the quality assurance measures in place in SPS, as well as implemented process improvement actions.

The OIG evaluated the new allegations of continuing issues with SPS reprocessing of RME, and did not substantiate that dirty instruments were sent to the operating room and approved for use by SPS leadership, that endoscopes were not being cleaned properly, or that loaner trays were not reprocessed appropriately. The OIG found no reported deficiencies related to RME reprocessed for use in the operating room during the period of the current inspection.

The OIG did not substantiate that SPS leaders failed to provide adequate oversight, quality control, education, and training to SPS staff. SPS leaders completed required VHA SPS certifications for their positions, and SPS leaders and education staff were sufficiently knowledgeable regarding the management of SPS and relevant standards.

The OIG did not substantiate the allegation that SPS leaders and education and training staff lacked appropriate knowledge to provide staff training. SPS leaders and education and training staff implemented relevant training plans and assessed staff competencies in accordance with VHA policy. In addition, SPS leaders conducted oversight of staff competencies per VHA policy.

Although the OIG noted instability within SPS leadership positions, the OIG found that facility leaders worked with VISN subject matter experts to ensure continuity of leadership in SPS when leadership vacancies existed. At the time of the inspection, facility leaders continued efforts to recruit a permanent candidate for the Chief of SPS position.

Across the course of interviews with leaders and staff, the OIG heard of challenges within SPS related to workplace culture. Based on the described challenges, along with the findings from this inspection, the OIG opined that individuals within SPS support the transitions in service leadership and changes associated with ongoing quality improvement efforts at varying degrees. As such, the resulting workplace culture may have factored into unsubstantiated negative perceptions of service leadership.

The OIG did not substantiate that SPS SOPs were chaotic and incomplete. The SPS SOPs were generally well-written and easy to follow with step-by-step instructions and illustrations. While the facility's overarching policy that addressed development of facility SOPs required updating to align with VHA policy and current facility practices, the OIG determined that since a revised draft of the facility policy was in the process of review and approval, a recommendation addressing remediation was unnecessary.

The OIG determined that both the VISN and facility leaders maintained adequate oversight, identifying and taking actions in response to concerns, and providing support for quality improvement efforts within SPS at the facility.

The OIG made no recommendations.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 10, 2022

From: Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Improvements in Sterile Processing Service and Leadership Oversight at the Edward Hines, Jr. VA Hospital in Hines, Illinois

To: Director, Office of Healthcare Inspections (54HL02)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to view the draft report of the Improvements in Sterile Processing Service and Leadership Oversight at the Edward Hines, Jr. VA Hospital in Hines, Illinois. I would like to thank the OIG Inspection team for a thorough review.

2. I concur with the report and conclusion of the OIG Inspection team.

(*Original signed by:*)

Daniel S. Zomchek, Ph.D., FACHE
Acting Network Director, VISN 12

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 2, 2022

From: Director, Edward Hines, Jr. VA Hospital (578)

Subj: Healthcare Inspection—Improvements in Sterile Processing Service and Leadership Oversight at the Edward Hines, Jr. VA Hospital in Hines, Illinois

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the Department of Veterans Affairs (VA) Office of Inspector General (OIG) draft report "Improvements in Sterile Processing Service and Leadership Oversight at the Edward Hines, Jr. VA Hospital in Hines, Illinois (MCI# 2022-00158-HI-1206)."
2. We thank the OIG Inspection team for their thorough review and concur with the report and conclusions.

(*Original signed by*:)

James Doelling
Medical Center Director, Edward Hines, Jr. VA Hospital

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